Supreme Court, U.S.
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IN THE

Supreme Court of the United States

LAHEY CLINIC HOSPITAL, INC.,
PETITIONER

v.

UNITED STATES OF AMERICA

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Did the Court of Appeals fail to comply with sound judicial practice when it failed to consider controlling questions of law within the scope of the Order that was certified by the District Court for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b)?

2. Under the circumstances of this case, did the Medicare Act, 42 U.S.C. §§ 1395 *et seq*, including its finality provisions at 42 U.S.C. § 405(h), deprive the District Court of subject matter jurisdiction over a claim based on federal common law brought by the United States of America to recover alleged overpayments to a Medicare provider?

3. Under the circumstances of this case, did the judicially developed doctrine of primary exclusive jurisdiction require the District Court to postpone the exercise of jurisdiction until the underlying issues relating to overpayments to a Medicare provider were determined by the Medicare agency?

4. Under the circumstances of this case, did the doctrines of ripeness or administrative exhaustion bar the exercise of jurisdiction to recover alleged overpayments to a Medicare provider when the Medicare agency had not yet determined that there was an overpayment amount for which the Medicare provider was liable?

CORPORATE DISCLOSURE STATEMENT

The Petitioner, Lahey Clinic Hospital, Inc., states that it has no corporate parent and that no publicly held corporation owns any stock in Lahey Clinic Hospital, Inc.

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PETITION FOR WRIT OF CERTIORARI

Lahey Clinic Hospital, Inc., the Petitioner, respectfully petitions this Court for a writ of certiorari to the United States Court of Appeals for the First Circuit to review its erroneous decision and opinion in Case No. 04-1753, decided February 4, 2005.

OPINIONS BELOW

The opinion of the Court of Appeals for the First Circuit is reported at 399 F.3d 1 (1st Cir. 2005) and reprinted in the Appendix at 1a-36a. The opinion and order of the United States District Court for the District of Massachusetts is not officially reported and is reprinted in the Appendix at 37a-43a. The opinion of the Court of Appeals also overruled the reasoning of the district court in *United States v. University of Massachusetts Memorial Medical Center*, 245 F. Supp. 2d 20 (D. Mass. 2003) which is reprinted in the Appendix at 44a-60a.

JURISDICTION

The Court of Appeals entered its decision on February 4, 2005. The Court has jurisdiction under 28 U.S.C. § 1254(1) to review the Court of Appeals' decision on a writ of certiorari.

RELEVANT STATUTES AND REGULATIONS

The following statutes and regulations involved in this case are set forth in the Appendix at 61a – 76a: 28 U.S.C. § 1292(b); 28 U.S.C. § 1345; 42 U.S.C. § 405 (g); 42 U.S.C. § 405(h); 42 U.S.C. § 1320c-1(1)(A); 42 U.S.C. § 1320c-3(a)(1) and (2); 42 U.S.C. § 1395g(a); 42 U.S.C. § 1395x(v)(1)(A)(ii); 42 U.S.C. § 1395ff(a)(1), (b)(1)(A) and (b)(1)(G); 42 U.S.C. § 1395ii; 42 U.S.C. § 1395kk(a); 42 U.S.C. § 1395kk-1(a)(1) and (4)(A); 42 U.S.C. § 1395pp(a); 42 CFR § 405.301; 42 CFR 405.371(a)(1) and (2); 42 CFR § 405.806; 42 CFR § 405.841; 42 CFR § 405.1803(c); 42 CFR § 405.1807; 42 CFR § 476.71(a)(1); 42 CFR § 476.86(a)(4); and 42 CFR § 421.100(c).

STATEMENT OF CASE

The Complaint in this case was filed in the United States District Court for the District of Massachusetts (the "District Court") by the United States of America ("United States") against Lahey Clinic Hospital, Inc. ("Lahey Clinic") seeking to recover alleged overpayments to a Medicare provider based on federal common law theories of unjust enrichment and payment by mistake. The United States alleged subject matter jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331 and averred that it was "acting through the Department of Health and Human Services" ("HHS"). The Secretary of HHS was not a party plaintiff.

In its Complaint, the United States averred that Lahey Clinic billed the Medicare program for over

88,000 medically unnecessary laboratory tests and miscoded another 9,300 tests between 1993 and 1996. The Secretary of the Department of Health and Human Services ("Secretary"), through its Fiscal Intermediary, made initial determinations pursuant to 42 U.S.C. § 1395ff(a) that Lahey Clinic should be paid the amounts that it received for every Medicare claim at issue. At no time has the Secretary decided to "re-open" or "revise" any of these initial determinations pursuant to 42 U.S.C. § 1395ff(b)(1)(G) and 42 CFR § 405.841. At no time has the Secretary, acting through an administrative contractor, made any "conclusive determination" that any of the claimed services were medically unnecessary as required by 42 U.S.C. § 1320c-3(a)(1) and (2) and 42 CFR § 476.71(a)(1). If the claims were medically unnecessary, the Secretary has not determined whether both the provider and the beneficiary "did not know and could not reasonably have been expected to know" that payment would not be made for these services as required by 42 U.S.C. § 1395pp(a) and 42 CFR § 476.86(a)(4). At no time has the Secretary, through its Fiscal Intermediary, determined that, if there was an overpayment, the Lahey Clinic was "without fault" and should be relieved of liability as required by 42 U.S.C. § 1395gg.[1] At no time has the Secretary, through its Fiscal Intermediary, determined after audit that there was an overpayment amount for which the Lahey Clinic is liable and issued a "retroactive corrective adjustment"

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[1] *See* Medicare Financial Management Manual, Chapter 3, § 100 (Rev. 12, 10-18-02) ("If the FI or carrier determines that an overpaid provider or physician was without fault, it relieves the provider of liability for the overpayment.") (available on line at *www.cms.hss.gov.*)

as required by 42 U.S.C. § 1395x(v)(1)(A)(ii) pursuant to Medicare's extensive "policies and procedures for handling of incorrect payments and recovery of overpayments." *See* 42 CFR § 405.301 and 42 CFR § 405.371(a)(1) and (2). The "initial determinations" by the Secretary have become final pursuant to the finality provisions in 42 U.S.C. § 405(h)[2] and the Secretary's finality regulations at 42 CFR § 405.806 and 42 CFR § 405.1807.

Lahey Clinic moved to dismiss the complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), Fed. R. Civ. P., and for a judgment on the pleadings pursuant to Rule 12(c), Fed. R. Civ. P. Lahey Clinic asserted that (1) the Court lacked subject matter jurisdiction because the first two sentences of 42 U.S.C. § 405(h) barred subject matter jurisdiction until the issues relating to an alleged overpayment first had been determined by the Medicare agency and its administrative review procedures had been exhausted as required by 42 U.S.C. § 405(g)[3]; (2) the judicially crafted doctrine of exclusive primary jurisdiction required an initial referral of the underlying overpayment issues to the Medicare agency; and (3) the claims were not justiciable based on application of the traditional doctrines of ripeness and administrative exhaustion.

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[2] Congress added 42 U.S.C. § 405(h) to the Medicare Act, 42 U.S.C. § 1395 *et seq.* ("the Medicare Act") by 42 U.S.C. § 1395ii.

[3] Congress added 42 U.S.C. § 405(g) to the Medicare Act by 42 U.S.C. § 1395ff(b)(1)(A).

The District Court denied the Motion to Dismiss in a Memorandum and Order dated April 30, 2004. (Appendix ("App.") at 37a - 43a). In its Memorandum the District Court certified its Order for an interlocutory appeal as follows:

> The Court is of the opinion that this Order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from this Order may materially advance the ultimate termination of the litigation.

(App. at 42a). Pursuant to 28 U.S.C. § 1292(b), Lahey Clinic filed a Petition for Permission to Appeal with the Court of Appeals for the First Circuit which was granted. On appeal Lahey Clinic raised the same three issues that it raised in the District Court. The Court of Appeals affirmed the decision of the District Court.

REASONS FOR GRANTING THE PETITION

I. THIS COURT SHOULD GRANT THE PETITION IN ORDER TO EXERCISE ITS SUPERVISORY POWERS TO CORRECT AN EXTREME DEPARTURE FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDINGS.

There are three distinct questions of law that relate to the correctness of the Order of the District Court which denied the Petitioner's Motion to Dismiss. These are: (1) whether the Medicare Act itself in 42

U.S.C. § 405(h) deprived the District Court of subject matter jurisdiction; (2) whether the judicially developed doctrine of primary exclusive jurisdiction required the District Court to postpone the exercise of its jurisdiction until the underlying issues relating to overpayments were determined by the Medicare agency; and (3) whether the judicially developed doctrines of ripeness or administrative exhaustion required the District Court to refrain from exercising jurisdiction until the underlying issue of the amount of any overpayment had been determined by the Medicare agency.

All three issues were raised both at the District Court and at the Court of Appeals. Nonetheless, the Court of Appeals addressed only the first issue. In its decision, it expressly held that the issue whether there should be a primary jurisdiction referral to the Medicare agency was not within its jurisdiction because it "is not within the scope of the certified question to us." 399 F.3d at 18. (App. at 27a.). It then stated that, if it had jurisdiction to consider that issue, "we see no basis on which to upset the District Court's Order." *Id.* With respect to the third issue relating to application of the doctrines of ripeness and administrative exhaustion, which the District Court expressly denied as a basis for dismissal, (App. at 42a), the Court of Appeals simply ignored it. The Court of Appeals plainly had jurisdiction pursuant to 28 U.S.C. § 1292(b) to consider and decide each of these questions because "[a]n appeal under this statute is from the *certified order* . . . ." *United States v. Stanley*, 483 U.S. 669, 677 (1987). *See also United States v. Fleet Factors Corp.*, 901 F.2d 1550, 1554 n.2 (11th Cir. 1990) ("When a district court certifies an order for

appeal, all questions material to the particular order are properly before the court of appeals," citing *United States v. Stanley, supra*). Because the Court's assertion that it was bound by a "certified question" is plain error and its failure to decide legal issues properly before it is "at odds with sound judicial practice," *United States v. Stanley, supra*, this Court should exercise its supervisory powers to correct this departure from the accepted and usual course of judicial proceedings.

Consistent with basic concepts of due process inherent in the federal court system for determining disputes, litigants expect and should have a right not only to be heard but also to obtain from the court its reasoning with respect to whether or not a legal principle appropriately applies to its case. Only when a court explains its view on the applicable rules of law is it possible for an appellate court to conduct a meaningful further review of the decision. The system of justice embodied in our federal court system requires that appellate courts that have jurisdiction over issues of law actually decide those issues and not simply ignore them. It is an injustice and failure of due process for an appellate court to refuse to decide issues that are clearly within its jurisdiction and which have been properly presented, fully briefed and argued.

II. THE BASIS FOR THE FINDING OF SUBJECT MATTER JURISDICTION CONFLICTS WITH DECISIONS OF THIS COURT AND IN OTHER CIRCUITS.

By passage of the Medicare Act, 42 U.S.C. § 1395 *et seq.*, Congress established a comprehensive administrative scheme that entrusts to the Secretary of the Department of Health and Human Services (the "Secretary") the exclusive responsibility to apply statutorily mandated substantive and procedural rules to determine how much a Medicare provider is to be paid for services. *See* 42 U.S.C. §1395g(a), 42 U.S.C. § 1395ff(a) and 42 U.S.C. §1395kk-1(a)(1) and (4)(A). If there is an overpayment, the Secretary is required to determine whether the provider is nonetheless entitled to keep that overpayment because it was "without fault" for the erroneous payment, or with respect to medically unnecessary services, because neither the beneficiary nor the provider knew "and could not reasonably have been expected to know" that payment would not be made. *See* 42 U.S.C. § 1395gg and 42 U.S.C. §1395pp. Pursuant to the review system mandated in 42 U.S.C. § 1395ff, the Secretary has established specific rules restricting the re-opening and review of initial payment determinations. *See* 42 CFR § 405.841. Pursuant to the finality provisions in the Medicare Act at 42 U.S.C. § 405(h), the Secretary's finality regulations make initial payment determinations final unless re-opened and revised by the Secretary. *See* 42 CFR § 405.806 and 42 CFR § 405.1807.

Despite the existence and comprehensive nature of these "rules of law," the United States and the Secretary, as the real party in interest, take the position that they do not have to comply with the Secretary's own regulations. Rather, they assert that the government may collaterally attack the administratively final payment determinations of the Medicare agency in a civil action based on federal common law. The United States suggests that a federal court, under the guise of applying judge-made principles of common law, may conduct its own *de novo* review of the Secretary's administratively final payment determinations. However, constitutional principles of due process do not allow the abandonment of the rule of law that results from ignoring lawfully promulgated regulations adopted pursuant to the express mandate of Congress. Under the *Accardi* doctrine, the failure of the Secretary to follow his own regulations is a violation of "due process." *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 268 (1954). Even the United States as sovereign may not ignore federal regulations. *United States v. Nixon*, 418 U.S. 683, 696 (1974) ("[s]o long as this regulation remains in force the Executive Branch is bound by it, and indeed the United States as sovereign composed of the three branches is bound to respect and enforce it.") The principle of finality, embodied in the doctrines of collateral estoppel and administrative *res judicata*, mandated by Congress in 42 U.S.C. § 405(h), and set forth in the Secretary's regulations at 42 CFR § 405.806 and 42 CFR § 405.1807, is rooted in both substantive and procedural due process principles. *McCuin v. Secretary of Health and Human Services*, 817 F.2d 161 (1st Cir. 1987). The failure by the Secretary to comply strictly with his own regulations

that limit when, and under what circumstances, his initial determinations may be re-opened results in lack of finality and violates due process. *Id.* at 172-175.

The conclusion of the Court of Appeals that there is subject matter jurisdiction over common law claims for recovery of Medicare overpayments, without first complying with the substantive rules and administrative procedures for review required by Congress and embodied in the Secretary's regulations, not only contravenes these well settled principles of constitutional due process but is in conflict with decisions of this Court and in other circuits.

The Court of Appeals' conclusion that 28 U.S.C. § 1345 was a sufficient source of subject matter jurisdiction for common law claims brought by the United States conflicts with this Court's decision in *Weinberger v. Salfi*, 422 U.S. 749 (1975). The Court of Appeals held that the requirements in 42 U.S.C. § 405(h) did not foreclose this other source of jurisdiction over the issue of whether the Medicare payments were correct. However, the second sentence of § 405(h) plainly states:

> "No findings of fact or decision of the [Secretary or the Department of Health and Human Services] shall be reviewed by any person, tribunal, or government agency except as herein provided."

The jurisdictional grant to the United States in 28 U.S.C. § 1345 expressly qualifies its grant of jurisdiction by stating "[e]xcept as otherwise provided by Act of Congress . . . ." In its decision in *Salfi*, *supra*,

this Court held that the first two sentences of § 405(h) "prevent review of decisions of the Secretary save as provided in the Act, which provision is made in s 405(g)." *Id.* at 757. Thus, § 405(h) forecloses jurisdiction based on any other statutory source of jurisdiction. In *Salfi*, with respect to certain plaintiffs who could not seek review under § 405(g), this Court concluded that there was still a lack of jurisdiction because "[o]ther sources of jurisdiction [were] foreclosed by § 405(h)." *Id.* at 764. Justice Stewart in his concurring opinion in *Califano v. Sanders*, 430 U.S. 99, 110-111 (1977) has explained why alternative sources of jurisdiction are precluded by § 405(h):

> ". . . I can see no reason in this case why the second sentence of [§ 405(h)] should not be read to mean exactly what it says that the decision before us is reviewable under [§ 405(g)] or not at all."
>
> * * *
>
> "[The second sentence of § 405(h)] simply requires that all review take place within the confines of the procedural scheme established by [§ 405(g)]. Section [405(h)] thus bars attempts to circumvent those procedures, whether by seeking review under [§ 405(g)] without having fulfilled the exhaustion requirement, or by seeking review under some other jurisdictional grant that does not prescribe the administrative steps that must first be taken."

Id. at 110-111 and FN*. Since in this case each initial determination of the Medicare agency approving each of the payments for the laboratory claims at issue clearly constitutes a "decision of the secretary" which is not eligible for review pursuant to § 405(g), the initial determinations in this case are "not [reviewable] at all" in federal court. *Id., see also Heckler v. Ringer*, 466 U.S. 602, 605 (1984) ("judicial review of claims arising under the Medicare Act is available only after the Secretary renders a 'final decision' on the claim, in the same manner as is provided in 42 U.S.C. § 405(g) for old age and disability claims arising under Title 2 of the Social Security Act.")

The Court of Appeals rejected the applicability of the principle of finality mandated by § 405(h) for two reasons, both of which create a conflict, not only with a prior decision of this Court, but also with the decisions in other circuits construing the meaning and applicability of the doctrine of administrative finality as embodied in and mandated by § 405(h).

First, the Court of Appeals held that § 405(h) simply did not apply and "a decision of the Secretary" was not implicated because § 405(g) and § 405(h) "do not apply where, as here, the Secretary has made neither findings of fact nor a decision after a hearing." 399 F.3d at 12. (App. at 16a). This interpretation of the concept of a "decision of the Secretary" is in conflict with this Court's explanation that even a "nonfinal [decision] is still a 'decision of the Secretary' which by virtue of the second sentence of § 405(h), may not be reviewed save pursuant to s 405(g)." *Salfi, supra*, 422 U.S. at 758 n6. The Court of Appeals' narrow view that § 405(h) is applicable only to decisions of the Secretary

"after a hearing" creates a conflict with decisions in other circuits which have held that the principles of finality embodied in § 405(h) apply to "initial determinations" even when there has not been a "decision after a hearing." *See Draper v. Sullivan*, 899 F.2d 1127, 1130 (11th Cir. 1990) (holding that the principal of administrative finality (*res judicata*) based on 42 U.S.C. § 405(h) applies to an "initial determination" of the Secretary which has become final because it was not reopened and revised by the Secretary and expressly rejecting the Secretary's argument that the doctrine of administrative finality (*res judicata*) did not apply because the agency was not acting in a judicial capacity and the parties did not have an opportunity to litigate the issues); and *Leviner v. Richardson*, 443 F.2d 1338, 1342 (4th Cir. 1971) (holding that "the doctrine of *res judicata* is applicable where no hearing was requested on the prior claim so that the Secretary's determination became final without a hearing.").

Secondly, relying on the third sentence in § 405(h), the Court of Appeals concluded that § 405(h) simply did not apply to an action brought by the government. 399 F.3d at 12. (App. at 16a - 17a). This limited view of the applicability of the finality doctrine as embodied in § 405(h) creates a conflict with decisions in other circuits. In addition to this case, *compare United States v. Aquavella*, 615 F.2d 12, 21 (2d Cir. 1979) ("§ 405(h) by its terms applies only to actions brought against the government and not by the government.") with *Drummond v. Commissioner of Social Security*, 126 F.3d 837, 842 (6th Cir. 1997) (holding that the principles of administrative finality required by 42 U.S.C. § 405(h) also apply against the

government); *Lively v. Secretary of Health and Human Services*, 820 F.2d 1391, 1392 (4th Cir. 1987) (holding that the "[p]rinciples of finality and fundamental fairness drawn from § 405(h)" apply equally to the Secretary and bar further proceedings in connection with prior determinations that have become final). *Cf. Far East Conference v. United States*, 342 U.S. 570, 576 (1952) (expressly rejecting the argument that there was jurisdiction because the United States brought the action because the "same considerations of administrative expertise apply, whoever initiates the action.")

III. THE DECISION OF THE COURT OF APPEALS NOT TO APPLY THE DOCTRINE OF EXCLUSIVE PRIMARY JURISDICTION CREATES A CONFLICT WITH DECISIONS OF THIS COURT AND IN OTHER CIRCUITS.

The Court of Appeals acknowledged that in the District Court's Order the request to the District Court for a "primary jurisdiction referral" had been denied but held that it had no jurisdiction to consider the issue. 399 F.3d at 18. (App. at 27a). Nonetheless, it stated "we see no basis on which to upset the District Court's Order." *Id.* Rejection by the Court of Appeals of the application of the doctrine of exclusive primary jurisdiction is in conflict with decisions of this Court and in other circuits.

Under this doctrine, decisions of this Court *require* federal courts to dismiss or postpone actions brought by the United States when underlying issues

appropriate for determination by an administrative agency based on its expertise have not been presented to and determined by that agency. *See Far East Conference v. United States*, *supra*, 342 U.S. at 574 and 576 (dismissing an antitrust action brought by the United States because the underlying issue was within the "exclusive preliminary jurisdiction" of the agency and "initial submission [of the issue] to the [agency] is required . . . ."); *United States v. Western Pacific Railroad Company*, 352 U.S. 59, 63-64 (1956) (holding that the tariff issues were "within the exclusive primary jurisdiction of the Interstate Commerce Commission."); *Whitney Nat'l Bank v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420 (1965) (citing *Far East Conference* , *supra*, and holding that "where Congress has provided statutory review procedures designed to permit agency expertise to be brought to bear on particular problems, those procedures are to be exclusive."); *cf. Bell v. New Jersey and Pennsylvania*, 461 U.S. 773 (1983) (holding that initial determinations of the existence and amount of any overpayments to states under a federal grant program were required to be done administratively based on an audit by the Department of Education.)

Application of the doctrine of primary jurisdiction was required precisely because Congress has provided in the Medicare Act specific statutory review procedures which allow the Medicare agency to apply its expertise to resolve the particular problems relating to whether the services are medically necessary and to whether there are overpayments for which a Medicare provider should be held liable. As a result, the Medicare agency's "procedures are to be exclusive." *Whitney*, *supra*, 379 U.S. at 420.

Congress has mandated that the Secretary, acting through its administrative contractors, "shall" determine the amounts of payments to providers. *See* 42 U.S.C. § 1395g(a) ("the Secretary shall periodically determine the amount which should be paid . . .") and 42 U.S.C. § 1395kk(a) (The Medicare program "shall be administered by the Secretary."). Congress has mandated that the "initial determinations" of the amounts of payments must be determined by the Secretary based on regulations issued by him. *See* 42 U.S.C. § 1395ff(a) ("The Secretary shall promulgate regulations and make initial determinations with respect to benefits under Part A or Part B in accordance with those regulations. . . ."). Congress has expressly mandated specific administrative procedures for making initial payment determinations, for the reopening and revision of initial determinations and for administrative hearings which allow for findings of fact. *See* 43 U.S.C. § 1395ff which the Secretary has implemented in extensive regulations. *See, e.g.*, 42 CFR Subpart G, Subpart H, and Subpart R. Congress has also mandated that the Medicare program is required to retroactively adjust its payments to hospitals and other providers because of prior overpayments. *See* 42 U.S.C. § 1395g(a) (requiring each year that the amount of Medicare reimbursement to a hospital must be determined "with necessary adjustments on account of previously made overpayments . . ."); 42 U.S.C. § 1395x(v)(1)(A)(ii) (requiring the Secretary to issue regulations that "provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or

excessive."). The Secretary has implemented the congressional mandate to recover overpayments by its procedures for offset and recoupment in 42 CFR, Subpart C, § 405.301 *et seq.* ("This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments."); *see also* 42 CFR § 405.371(a)(1) and (2) and 42 CFR § 405.1803(c).[4] With respect to the underlying issues relating to the medical necessity of services, Congress has mandated a specific review procedure that requires experts to make the determinations. *See* 42 U.S.C. § 1320c-3(a)(1) and (2) (requiring that decisions relating to whether or not services were "medically necessary" must be made by administrative contractors whose determinations "shall constitute the conclusive determination on those issues for purposes of payment under Title XVIII . . . ."). Such organizations are required by Congress to be composed of licensed doctors of medicine who are required to make the decisions relating to medical necessity. *See* 42 U.S.C. § 1320c-1 and 42 U.S.C. § 1395ff(c)(3)(B)(i) (contractors must use a "panel of physicians or other appropriate health care professionals"). The Secretary by regulation has implemented this special review procedure. *See* 42

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[4] Under the circumstances of this case, these administrative procedures even now allow the Secretary to fully recover any established overpayments made in prior years to the Lahey Clinic. *See In re Holyoke Nursing Home, Inc.*, 372 F.3d 1, 5 (1st Cir. 2004) ("[the Medicare program] has the unqualified right to recoup these overpayments *in full* and to return these funds to the public fisc. . . ."); *In re Slater Health Center*, 398 F.3d 98, 104 (1st Cir. 2005) ("Congress intended, in the Medicare statutes, for the Medicare payment adjustment system to operate as one continuous stream, including 'overpayments' (a term that the Secretary has power to define). 42 U.S.C. § 1395g(a); 42 U.S.C. § 1395x(v)(1)(A)").

CFR, Subpart B, § 476.70 *et seq.*; *see also* 42 CFR § 476.71(a)(1). With respect to the Congressional mandate that the Secretary determine whether a provider may keep an overpayment for a medically unnecessary service, as required by 42 U.S.C. § 1395pp, the Secretary by regulation has made the determination of the administrative contractor "conclusive for payment purposes." *See* 42 CFR § 476.86(a)(4) ("QIO determinations as to whether the provider or beneficiary knew or could reasonably be expected to have known that the services [found to be medically unnecessary] were excluded are also conclusive for payment purposes.")

Because Congress has specified these very particularized review procedures relating to the determination and recovery of overpayments, as well as medical necessity determinations, these "procedures are to be exclusive." *Whitney*, *supra*, 379 U.S. at 420. *Cf. United States v. Babcock*, 250 U.S. 328, 331 (1919) ("[W]here a statute creates a right and provides a special remedy, that remedy is exclusive."); *Switchmen's Union of North America v. National Mediation Board*, 320 U.S. 297, 301 (1943) ("[I]t is for Congress to determine how the rights which it creates shall be enforced . . ." and in "such a case the specification of one remedy normally excludes another."); *Mobil Oil Corporation v. Higginbotham*, 436 U.S. 618 (1978) (holding that, because the High Seas Act spoke directly to the issue of damages, general maritime law providing for other types of damages could not be used to supplement the more restrictive remedies sanctioned by the Act itself.)

The Court of Appeals' apparent belief that application of the doctrine of exclusive primary jurisdiction was a prudential, discretionary matter for the District Court is in conflict with decisions of the Court of Appeals for the Ninth Circuit. *See United States v. Yellow Freight System, Inc.* 762 F.2d 737, 739 (9th Cir. 1985) (holding that application of the doctrine is a question of law subject to *de novo* review and failure to defer when the doctrine so mandates is reversible error); *United States v. General Dynamics Corp.*, 828 F.2d 1356, 1364 n.15 (9th Cir. 1987) (noting that application of the doctrine is not discretionary and the "issue either is within an agency's primary jurisdiction or it is not . . . ."). The failure of the Court of Appeals to apply the doctrine of exclusive primary jurisdiction under circumstances in which its application was required conflicts with both the decisions of this Court and those in another circuit.

IV. THE DECISION OF THE COURT OF APPEALS NOT TO APPLY THE TRADITIONAL DOCTRINES OF ADMINISTRATIVE EXHAUSTION AND RIPENESS CONFLICTS WITH DECISIONS OF THIS COURT AND IN OTHER CIRCUITS.

The District Court's Order expressly refused to find lack of justiciability under the traditional doctrines of administrative exhaustion and ripeness. (App. at 42a). The Court of Appeals recognized that this issue was presented to it by Petitioner. 399 F.3d at 8. (App. at 9a-10a). It also noted that the issue was a matter of subject matter jurisdiction. 399 F.3d at 8 n.6. (App. at 29a). However, the Court of Appeals did not discuss

the issue at all in its opinion. Petitioner assumes, therefore, that the Court of Appeals found the doctrines inapplicable to bar subject matter jurisdiction based on lack of justiciability. This decision conflicts with the decisions of this Court and with the decisions in other circuits.

Whether or not § 405(h) constitutes an express jurisdictional bar, this Court has unequivocally held that at least the traditional doctrines of administrative exhaustion and ripeness are applicable to Medicare disputes as a result of the first two sentences in § 405(h). As this Court held in *Weinberger v. Salfi*, *supra*, 422 U.S. at 757, "the first two sentences of § 405(h) . . . assure that administrative exhaustion will be required." The traditional doctrine of ripeness is also applicable to Medicare disputes. *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 12-13 (2000) (approving of the application of ordinary principles of both ripeness and exhaustion to Medicare disputes and noting with approval that the Court of Appeals had applied the doctrine of ripeness to many of the claims). "[T]he traditional ripeness doctrine. . . often requires initial presentation of a claim to an agency." *Id.* at 20. "At a minimum, however, the matter must be presented to the agency prior to review in federal court." *Id.* at 24. This requirement of initial presentment of the matter to the Medicare agency is a "nonwaivable and nonexcusable requirement." *Id.* at 15. Since the issues of medical necessity and the amount, if any, of overpayments have not been presented to and determined by the Medicare agency, this action is not ripe for adjudication in a federal court.

The application of the doctrine of ripeness in this case meets the criteria specified by this Court in *Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998). First, there is no hardship to the plaintiff. If there were overpayments for which Lahey Clinic is liable, the administrative procedures will expertly so conclude and retroactive overpayment adjustments can be made so that any amount of actual overpayment for which Lahey Clinic is liable will be fully returned to the Medicare program. Secondly, judicial intervention now poses a serious risk of inappropriately interfering with further administrative action. For the over 9,000 claims that the government contends were improperly coded, the judgment of a court on this disputed issue "could hinder agency efforts to refine its policies." *Id.* at 735. Finally, the court "would benefit from further factual development of the issues presented." *Id.* at 733. For the over 88,000 claims the government asserts were not medically necessary, use of the congressionally mandated review by agency experts, *i.e.* physicians, would relieve the court of "time-consuming judicial consideration," *id.* at 736, of issues that require specialized expertise not within the usual experience of judges or juries.

The failure of the Court of Appeals to hold that there was a lack of justiciability based on the traditional doctrine of ripeness puts it in conflict with decisions in other circuits that have held that no claim by the government to recover a Medicare overpayment even accrues until the Medicare agency conducts an audit to determine the amount of an overpayment and issues a final retroactive adjustment. *See United States v. Gravette Manor Homes, Inc.*, 642 F.2d 231, 244 (8th Cir. 1981) (holding that no right of action had

accrued "until a final determination of liability had been made by the intermediary" based on an audit and that "the government's cause of action accrues with the making of the final retroactive adjustment . . . which sets the exact amount of overpayment or underpayment due from or to the provider."); *United States v. Withrow*, 593 F.2d 802 (7th Cir. 1979) (government action to recover Medicare overpayments only accrues when a Fiscal Intermediary's final audit determines the amount of overpayment); *United States v. Pisani*, 646 F.2d 83 (3d Cir. 1981) (same); *see also U.S. v. Hughes House Nursing Home, Inc.* (Breyer, J.), 710 F.2d 891, 893-894 (1st Cir. 1983) (". . . [N]o statute, rule or regulation gives the government any right to collect any additional overpayment of the sort described above before a final audit, formally determining its existence, takes place.") If recoupment actions do not even accrue until the Fiscal Intermediary conducts an audit to determine the amount of any overpayment and issues a final determination that an overpayment exists, the absence in this case of that audit[5] and final determination makes the claim for repayment of alleged overpayments unripe for consideration by a federal court. Thus, the refusal of the Court of Appeals to apply the doctrine of ripeness conflicts with the decisions of courts of appeals in other circuits.

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[5] *See* 42 CFR § 421.100(c) ("The intermediary must audit the records of providers of services as necessary to assure proper payments.").

CONCLUSION

The decision of the Court of Appeals presents difficult and thorny issues relating to the finality of administrative decisions and the subject matter jurisdiction of federal courts. There is a lack of uniformity of decisions in the circuits on these issues. Your Petitioner respectfully requests that this Court grant its petition for a writ of certiorari so that these important issues of law may be resolved.

Respectfully submitted,

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(Any footnotes trail end of each document)

No. 04-1753

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff, Appellee,

v.

LAHEY CLINIC HOSPITAL, INC.,
Defendant, Appellant.

February 4, 2005, Decided

COUNSEL: Richard P. Ward, with whom Ropes & Gray LLP was on brief, for appellant.

Jeffrey Clair, Attorney, Civil Division, United States Justice Department, with whom Peter D. Keisler, Assistant Attorney General, Michael J. Sullivan, United States Attorney, Douglas N. Letter, and Nancy Rue, Attorneys, Civil Division, United States Justice Department, were on brief, for appellee.

JUDGES: Before Lynch, Lipez, Howard, Circuit Judges.

OPINION BY: LYNCH

OPINION: LYNCH, Circuit Judge. The United States filed a civil complaint in federal district court under 28 U.S.C. § 1345 alleging that the Lahey Clinic Hospital

billed Medicare and received payment for tests and other diagnostic procedures performed by its clinical laboratory when Lahey knew, or reasonably should have known, that the tests were not reasonable and necessary for diagnosis or treatment of illness or injury of Medicare beneficiaries. The United States sought restitution for these overpayments, including an accounting, disgorgement of improper gains of over $ 311,000, and prejudgment interest, under common law theories of unjust enrichment and payment under mistake of fact.

Lahey moved for judgment on the pleadings and, in the alternative, for summary judgment. Lahey argued that the Medicare Act, 42 U.S.C. § 1395, et seq., and the attendant administrative procedures promulgated by the Secretary of Health and Human Services (HHS), are the exclusive avenue for recovery by the United States of Medicare overpayments, and as such, the district court had no subject matter jurisdiction. The court denied the motion and certified the question of subject matter jurisdiction to this court under 28 U.S.C. § 1292(b).

On interlocutory appeal, the question presented is whether the district court lacks subject matter jurisdiction because the Medicare Act explicitly or implicitly repeals the grant of federal court jurisdiction under 28 U.S.C. § 1345 or displaces the underlying common law causes of action over which § 1345 gives federal courts jurisdiction. We hold that the Medicare Act does not repeal 28 U.S.C. § 1345 or displace the underlying common law causes of action. We affirm.

I.

Congress established the Medicare program in 1965 by Title XVIII of the Social Security Act. 42 U.S.C. § 1395 et seq. Medicare is a federally subsidized health insurance program for the elderly and certain disabled individuals. See id. § 1395c. The Secretary of HHS is responsible for the Medicare program, and during the time period relevant to this case, the Health Care Financing Administration (HCFA) n1 was the component of HHS responsible for administering the Medicare program.

Medicare is divided into two parts: Part A and Part B. Part A provides insurance for covered inpatient hospital and related post-hospital services. Part B provides voluntary and supplementary insurance which covers physicians' and certain other medical and health services, including laboratory tests administered by a hospital and furnished to outpatients for the purpose of diagnosis. Id. §§ 1395j, 1395k, 1395x(s). The Secretary contracts with "fiscal intermediaries" (FIs) and "carriers" to make initial reimbursement determinations and to administer payments. These entities are often private insurance companies. In most circumstances, FIs administer Part A and carriers administer Part B, but FIs administer the program with respect to hospitals for outpatient services covered under Part B.

The claims here concern payments for services provided under Part B of Medicare. During the relevant time period involved in this case, these payment decisions were made "by the Secretary in accordance with the regulations prescribed by him." Id.

§ 1395ff(a). In order to be reimbursed through Medicare Part B, participating providers must first file a claim with their FI. As for the services involved in this case, they must be reasonable and necessary for diagnosis or treatment of illness or injury; they were covered only if ordered by a treating physician who used the test results in the management of the beneficiary's specific medical problem. 42 C.F.R. § 410.32. Once a payment decision has been made, a dissatisfied provider may seek administrative review of this determination and then judicial review of the Secretary's final decision after the avenues of administrative appeal have been exhausted. Id. § 1395ff(b)(1).

In the late 1980's, Medicare's escalating payments for laboratory services became a source of increasing concern to Congress, the Secretary, and HHS's Office of Inspector General. In legislation that took effect in 1986, Congress imposed payment caps on the amount individual carriers could pay in reimbursement for laboratory services. See 42 U.S.C. 1395l(h). Nonetheless, payments for Part B laboratory services continued to rise, reaching $ 3.9 billion in fiscal year 1987.

In response to these rising costs, in 1990, the HHS Inspector General (IG) conducted a review of a sample of Medicare billings for the year 1988 and determined that Medicare was paying nearly twice as much as physicians for the same tests. The IG found that much of the added cost was attributable to Medicare's reimbursement of panels of tests. These tests were bundled together and performed at the same time, as an integrated group. The IG found that when physicians ordered these panels of tests, they were

billed at a reduced rate to account for savings from performing the tests as a group. However, when Medicare was billed for these tests, the individual tests within the panel were billed separately at their full rate, resulting in greatly increased costs to Medicare.

A 1998 audit by the IG found the same problem in claims for clinical tests performed by hospital laboratories serving outpatients. The 1998 audit also raised concerns about certain hematology indices, which can be generated from the results of other tests. The report concluded that in many instances these indices were automatically prepared when other related tests were ordered and then separately billed to Medicare, even if the index was duplicative or medically unnecessary.

Within the narrow category of services of clinical laboratory tests performed by hospital outpatient laboratories, including chemistry, hematology, and urinalysis tests, the IG found that "Medicare FIs overpaid hospital outpatient department laboratories about $ 43.6 million . . . during a two year period from January 1, 1994 to December 31, 1995." The IG found for that same time period "an additional $ 15.6 million could have been saved if policies had been developed to preclude payment for additional automated hematology indices."

Accordingly, the IG recommended that the Secretary implement controls to stop these overpayments and seek to recover overpayments previously made. The Secretary agreed and noted that he would "coordinate any recovery activity with the Department of Justice through our Office of General Counsel." A number of

civil actions have been instituted to recover some of these costs under various theories. See, e.g., United States v. Blue Cross & Blue Shield of Ala., 156 F.3d 1098 (11th Cir. 1998) (False Claims Act); United States v. Tenet Healthcare Corp., 343 F. Supp. 2d 922 (C.D. Cal. 2004) (common law mistake and negligent misrepresentation). The current dispute between Lahey and the United States arose against this background.

We are careful to say that Lahey does not argue that the United States may not recover overpayments, only that it has chosen the wrong approach in doing so. n2 Similarly, the United States has not alleged fraud on Lahey's part in this action. Lahey is a renowned academic medical center that participates in the Medicare program as a "provider of services" to Medicare beneficiaries. Lahey has entered into a provider agreement with the Secretary pursuant to 42 U.S.C. § 1395cc. The agreement provides that Lahey will be reimbursed by Medicare through Blue Cross/Blue Shield of Massachusetts (Lahey's FI during the relevant time period) for medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

On January 30, 2003, the United States filed an action under 28 U.S.C. § 1345 n3 against Lahey alleging "violations of the common law giving rise to causes of action for unjust enrichment and payment under mistake of fact." The allegations were split into two different groups. The first group asserted that Lahey "repeatedly billed Medicare for separate individual

laboratory tests that could practically and more economically be performed as a single panel of tests." This billing practice violated Medicare reimbursement policies which required the tests to be billed as "an integrated, single panel of tests rather than separately." The government also alleged that Lahey knew or should have known of this reimbursement requirement and that Lahey nonetheless submitted numerous individual claims between July 1, 1993 and June 30, 1994. In total, the United States stated that Lahey submitted over 9,300 Medicare claims for unbundled blood chemistry tests.

A second group of allegations asserted that virtually every time a complete blood count test was ordered for a patient and Lahey billed the United States for this test, Lahey performed a medically unnecessary hematology test. Specifically, between July 1, 1993 and December 31, 1996, Lahey submitted over 88,000 claims for payment of certain "automated hemogram indices," which were generated every time a complete blood count was ordered. The United States alleges that Lahey repeatedly billed Medicare for these tests without making any determination that they were medically necessary or actually sought by the treating physician and that in fact these tests were rarely medically useful.

Lahey moved for judgment on the pleadings or in the alternative, summary judgment, primarily arguing that the district court did not have subject matter jurisdiction because Medicare's jurisdictional provisions, specifically 42 U.S.C. §§ 405(h) and 405(g), bar the United States from seeking to recover a prior overpayment through a direct action in federal court.

Lahey asserted that the initial decision by the FI to reimburse Lahey for the tests is a final decision of the Secretary, and this final decision can only be reopened by the Secretary through the processes and procedures outlined in the Medicare Act and the regulations promulgated pursuant to it.

Finding that it had subject matter jurisdiction, the district court denied Lahey's motion on March 25, 2004. The court held that the statutory provisions in the Medicare Act apply to claims brought against the United States not claims brought by the United States as plaintiff. The district court based its decision on several factors: the language of the statutory provisions; the decision in United States v. Aquavella, 615 F.2d 12, 21 (2d. Cir. 1979), which concluded that "§ 405(h) by its terms applies only to actions brought against the government and not by the government"; and that the policy reasons for requiring administrative review are not implicated when the government is the plaintiff.

Lahey requested that the district court certify its order for interlocutory appellate review. On April 30, 2004, the district court amended its prior order and certified the issue for interlocutory appeal under 28 U.S.C. § 1292(b), stating that the denial of summary judgment involved "a controlling question of law as to which there is a substantial ground for difference of opinion and that an immediate appeal from this Order may materially advance the ultimate termination of the litigation." n4 Lahey then petitioned this court for permission to take an interlocutory appeal, and framed the question presented as whether "Lahey Clinic Hospital, Inc. [is] entitled to dismissal pursuant to Fed. R. Civ. P., Rule

12(b)(1) because the Court lacks subject matter jurisdiction." This court granted permission to appeal on June 9, 2004, and we have jurisdiction pursuant to 28 U.S.C. § 1292(b).

II.

Lahey's opening brief to us argues that the district court lacks subject matter jurisdiction because:

By virtue of the incorporation of §§ 405(g) and 405(h) into the Medicare Act, federal district courts only have subject matter jurisdiction to review Medicare payment decisions that have initially been presented to and determined by the Secretary and any such determinations have been fully reviewed under the Secretary's regulations establishing administrative review procedures. Only after the Secretary has made a "final decision" after affording the provider of services an administrative evidentiary hearing to determine the many factual issues that bear on whether under applicable Medicare principles there were any overpayments for which the provider is liable, does a federal court have jurisdiction to review a decision of the Secretary.

These preliminary procedures did not take place, and therefore, Lahey argues, the district court does not have subject matter jurisdiction.

Lahey also argues that the district court lacks subject matter jurisdiction for a number of other reasons: (1) the judicially established doctrines of exclusive or primary jurisdiction; (2) the lack of justiciability under the doctrines of ripeness and exhaustion of

administrative remedies; (3) exercising jurisdiction in this case would deprive Lahey of procedural due process mandated by the Medicare Act; n5 and (4) the United States failed to meet its burden of proof to present sufficient facts to establish subject matter jurisdiction. n6

Lahey's order of argument is misplaced. Each of its arguments assumes the premises that the Medicare Act is the only avenue available to the United States to recover Medicare overpayments and that the Act repeals the grant of federal court jurisdiction under § 1345 and displaces the underlying common law causes of action. We first address whether those premises are correct.

Subject matter jurisdiction in this case is barred by the Medicare Act only if Congress in enacting the Medicare Act has removed federal court jurisdiction over these claims brought by the United States as plaintiff under 28 U.S.C. § 1345. A related issue is whether the Medicare Act displaced the underlying common law causes of action relied on by the government in this case to exercise its right to recover payments wrongfully made out of the public fisc. Congress undoubtedly has the ability to do both of these actions. See Colorado River Water Conservation Dist. v. United States, 424 U.S. 800, 47 L. Ed. 2d 483, 96 S. Ct. 1236 (1976); City of Milwaukee v. Illinois, 451 U.S. 304, 68 L. Ed. 2d 114, 101 S. Ct. 1784 (1981).

But if Congress has not acted in this manner, then Lahey's argument, concerning the need for a final overpayment decision that was initially presented to and determined by the Secretary and was fully

reviewed under the Secretary's administrative regulations prior to the exercise of federal court jurisdiction, is irrelevant. n7 The federal court has an independent jurisdictional grant under § 1345 and the United States has an independent cause of action for recovery under the common law.

We now turn to those two critical issues and treat them as corollary. Both are pure questions of law, and our review is de novo. P.R. Tel. Co. v. Telecomm. Regulatory Bd. of P.R., 189 F.3d 1, 7 (1st Cir. 1999).

28 U.S.C. § 1345 grants broad jurisdictional power to the district courts over suits when the United States is plaintiff. The statute provides:

Except as otherwise provided by Act of Congress, the district courts shall have original jurisdiction of all civil actions, suits, or proceedings commenced by the United States or by an agency or officer thereof expressly authorized to sue by Act of Congress.

28 U.S.C. § 1345. n8

Section 1345 creates subject matter jurisdiction, and the statute can only be limited, as the initial proviso provides, by (1) an explicit repeal of the statute by an Act of Congress or (2) an implicit repeal by total irreconcilability of the two acts. See Colorado River, 424 U.S. at 808. Repeal of a federal statute by implication is disfavored, and the individual arguing for repeal has the burden of showing that the statute has been repealed. Cf. King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (burden on the individual arguing for preemption of state law to show that the law is

preempted). The intention of Congress to repeal must be clear and manifest. Radzanower v. Touche Ross & Co., 426 U.S. 148, 154, 48 L. Ed. 2d 540, 96 S. Ct. 1989 (1976). There is a strong presumption against implied repeals of federal statutes, see Kremer v. Chemical Constr. Corp., 456 U.S. 461, 468, 72 L. Ed. 2d 262, 102 S. Ct. 1883 (1982); United States v. Commonwealth of Puerto Rico, 721 F.2d 832, 836 (1st Cir. 1983), and this presumption is perhaps an even stronger one when the repeal is a grant of jurisdiction to the federal courts. Where, in particular, the subject matter jurisdiction of the federal courts is involved, jurisdiction "should not be disturbed by mere implication from the subsequent legislation." Colorado River, 424 U.S. at 808 (quoting Rosencrans v. United States, 165 U.S. 257, 262, 41 L. Ed. 708, 17 S. Ct. 302 (1897)).

To show an explicit repeal of a grant of federal court jurisdiction under § 1345, Lahey must point to a later enacted statute which by its terms explicitly repeals this jurisdiction.

Second, if Congress has not explicitly repealed § 1345, then Lahey must point to total irreconcilability with a later statute or, perhaps, that the later act was meant as a substitute by covering the whole subject matter.n9

Kremer, a case not involving the repeal of a grant of federal court jurisdiction, sets forth a two-part test for implied repeals of federal statutes:

(1) where provisions in the two acts are in irreconcilable conflict, the later act to the extent of the conflict constitutes an implied repeal of the earlier one; and (2) if the later act covers the whole subject of the earlier

one and is clearly intended as a substitute, it will operate similarly as a repeal of the earlier act. But, in either case, the intention of the legislature to repeal must be clear and manifest. . . .

Kremer, 456 U.S. at 468 (citing Radzanower v. Touche Ross & Co., 426 U.S. at 154 (quoting Posadas v. Nat'l City Bank, 296 U.S. 497, 503, 80 L. Ed. 351, 56 S. Ct. 349 (1936))). We assume in Lahey's favor that both prongs of the Kremer test are available for all aspects of its claims. In shorthand terms, to show an implicit repeal of § 1345, Lahey must show that (1) the provisions of § 1345 are in irreconcilable conflict with the Medicare Act or (2) the Medicare Act, by clear and manifest intent, covers the whole subject matter area and was meant as a substitute.

As for Lahey's second claim that a federal statute displaces the federal common law, "the relevant inquiry is whether the statute [speaks] directly to [the] question otherwise answered by the common law." See County of Oneida v. Oneida Indian Nation, 470 U.S. 226, 237, 84 L. Ed. 2d 169, 105 S. Ct. 1245 (1985) (quoting City of Milwaukee, 451 U.S. at 315) (internal quotation marks omitted). Although the Court recognized that Congress need not "affirmatively proscribe" the common law doctrine at issue, see United States v. Texas, 507 U.S. 529, 534, 123 L. Ed. 2d 245, 113 S. Ct. 1631 (1993) (quoting City of Milwaukee, 451 U.S. at 315), still "statutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles . . . ." Id. (quoting Isbrandtsen Co. v. Johnson, 343 U.S. 779, 783, 96 L. Ed. 1294, 72 S. Ct. 1011 (1952)).

To show displacement of the common law causes of action relied on by the United States to recover money wrongfully paid by the Treasury, Lahey must overcome this presumption and demonstrate that Congress has directly addressed the issue and that Congress intended to preclude the United States from assertion of common law rights to recover overpayments by enactment of the Medicare Act. Inconsistency between the two statutes (or claimed inconsistency of a statute with common law) is not enough: "where two seemingly inconsistent acts can reasonably stand together, a court must interpret them in a manner which gives harmonious operation and effect to both, in the absence of clear and unambiguous expression of Congressional intent to the contrary." United States v. Kenaan, 557 F.2d 912, 917 (1st Cir. 1977) (citing Morton v. Mancari, 417 U.S. 535, 549-51, 41 L. Ed. 2d 290, 94 S. Ct. 2474 (1973)).

A. Explicit Repeal of Section 1345

Lahey asserts that jurisdiction under § 1345 is expressly limited by the introductory proviso that states: "Except as otherwise provided by Act of Congress . . . ." 28 U.S.C. § 1345. Lahey argues that §§ 405(g) and 405(h), of the Medicare Act, 42 U.S.C. § 1395ff(b) and 42 U.S.C. § 1395ii respectively, repeal the jurisdictional grant of § 1345 as they are "Acts of Congress" that come within this limiting proviso.

Section 405(g) provides for judicial review in the federal courts of the Secretary's final administrative decision by an individual. The relevant part of § 405(g) states as follows:

(g) Judicial Review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia.

42 U.S.C. § 405(g). n10

Lahey argues that § 405(h), in turn, makes § 405(g) the exclusive avenue for judicial review of the Secretary's final determinations. Section 405(h) provides:

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331

or 1346 of Title 28 to recover on any claim arising under this subchapter.

Id. § 405(h).

Specifically, Lahey points to the second sentence in § 405(h) -- "no findings of fact or decision of the [Secretary of HHS] shall be reviewed by any person, tribunal, or governmental agency except as herein provided" -- and argues the language manifests an express congressional intent to repeal § 1345 in decisions regarding the payment or overpayment of Medicare claims. Lahey contends that the initial payment decision to reimburse Lahey for the tests is "a decision of the Secretary" and § 405(h) makes § 405(g) the exclusive avenue for judicial review of this decision, regardless of whether the plaintiff is the United States or a dissatisfied beneficiary or provider.n11

The argument fails. By its terms, neither the sentence Lahey cites nor § 405(h) as a whole mention § 1345. Also, they do not apply where, as here, the Secretary has made neither findings of fact nor a decision after a hearing. The United States is not asking the federal courts to review a decision of the Secretary, it is bringing an independent action to establish the United States' right to obtain restitution of monies wrongfully paid from the public fisc.

Indeed, by its terms, § 405(h) is more consistent with congressional intent to preserve jurisdiction under § 1345. The third sentence of § 405(h) is explicit that no action "against the United States . . . shall be brought under § 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h)

(emphasis added). Section 405(h) does not refer to actions brought by the United States or actions brought under 28 U.S.C. § 1345. And § 405(g), the terms of which Lahey argues are the exclusive route to judicial review, refers to "individuals," not to the "United States."

Lahey's argument is also inconsistent with Colorado River, which involved the question of whether the same statute here at issue, 28 U.S.C. § 1345, had been repealed by the McCarran Amendment. Colorado River, 424 U.S. at 807-09. The Court noted that the McCarran Amendment did contain some limitations but, as here, did not mention § 1345. The court concluded that the statute by its terms did not "indicate any repeal of jurisdiction under § 1345." Id. at 807.

A reading of the text of the statute alone may not be dispositive of the explicit repeal question. When determining the intent of Congress, Colorado River at least encourages n12 a further examination of the legislative history of the Medicare Act to see if it evidences "a clear purpose to terminate any portion of § 1345 jurisdiction." Id.; see also Commonwealth of Puerto Rico, 721 F.2d at 836. The United States argues that "the fundamental purpose of Medicare's jurisdictional scheme is to channel all claims pressed by dissatisfied providers or beneficiaries through a detailed process of administrative review before such claims are presented in federal court." See Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 13, 146 L. Ed. 2d 1, 120 S. Ct. 1084 (2000) (The Medicare scheme requires the "channeling" of "virtually all legal attacks" on the Secretary's decisions and determinations through the agency.).

Lahey has provided no legislative history in support of its argument that Congress intended to repeal jurisdiction under § 1345. Nor has it refuted the government's assertions as to the purpose of the review provisions. The burden is on Lahey, and it does not meet its burden. Our own review shows the legislative history supports the government's position. The 1965 Amendments to the Social Security Act established the Medicare program and the appeals process for payment determinations. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965). Senate Report 89-404 accompanies this law. S. Rep. No. 89-404. The Senate Report is void of any expression by Congress of intent to repeal federal court jurisdiction under § 1345. Instead, the report focuses on the need for the appeals process in order for the individual to challenge the determinations of the Secretary. Id. at 58.

B Implied Repeal of § 1345 and Displacement of Common Law

Even if Lahey cannot prevail on the express repeal prong, a second avenue of argument is available: that Congress impliedly repealed § 1345 jurisdiction. Lahey also argues that Congress displaced the underlying common law causes of action as to claims by the United States for recovery of Medicare overpayments.

We understand Lahey to argue as follows: Congress authorized the Secretary of HHS to recover Medicare overpayments and to promulgate regulations to this end. Those regulations provide detailed procedures under which providers can challenge decisions made by the Secretary. The law is clear that a provider must make an initial presentation to the agency, which then

must make a final determination, before there is any federal court review. The law is also clear that once this initial payment decision is final, in order to reopen it, the Secretary must follow established procedures. As a result, the administrative claims procedure is in irreconcilable conflict with § 1345 and it speaks directly to and hence displaces the United States' independent action for restitution. According to Lahey, under the provisions of the Medicare Act, only the Secretary, in accordance with established procedures, may collect overpayments because only the Secretary can make and reopen final payment determinations, not the Department of Justice. In other words, the detailed remedies for recoupment established under the statute are exclusive and cannot be bypassed by the Department of Justice.

Lahey argues that "under the Medicare Act and its supplementary regulations, Congress has provided for very specialized remedies relating to and dealing with the recoupment of any overpayment." Lahey's argument of implied repeal of § 1345 and displacement of common law rests entirely, not on the Medicare Act itself, but on a supposed conflict between suit to recover overpayment under § 1345 and an administrative remedial scheme for collection of overpayments, see 42 C.F.R. §§ 405.370, 405.371, 405.372, promulgated by the Secretary to carry out the purposes of 31 U.S.C. § 3711 and 42 U.S.C. § 1395g. The argument is based on a fundamental misunderstanding.

Congress could, perhaps (we need not decide), attempt to expressly provide for repeal of a statute or displacement of the common law through delegation of such power to an agency. But Congress has not done so

here. In the absence of such a delegation, a statute, § 1345, cannot be repealed by administrative regulation from an executive branch agency. First, § 1345 by its terms states, "except as otherwise provided by Act of Congress"; it does not state "except as provided by administrative regulation of an agency." In addition, the tests for implied repeal established through the case law involve congressional intent, not the intent of an agency's regulations, regardless of how extensive they are. As for displacement of common law, the tests concern whether Congress directly spoke to the issue and whether Congress intended to deprive the government of a longstanding power. Thirdly, to permit an agency by its actions to repeal an act of Congress or displace a long standing power of the United States would pose grave constitutional questions of violation of separation of powers. Cf. Clinton v. New York, 524 U.S. 417, 141 L. Ed. 2d 393, 118 S. Ct. 2091 (1998).

There is nothing in the Medicare Act which establishes that the administrative remedy chosen by the Secretary here to collect overpayments and the limited judicial review provided for in §§ 405(b) and 405(h) are mandated by Congress as the exclusive remedy or that Congress delegated any such a choice to the Secretary.n13

As to the implied repeal of § 1345, we reject Lahey's argument that an irreconcilable conflict arises from the fact that in §§ 405(h), 405(g), and 42 U.S.C. § 1395oo n14 Congress deprives the federal courts of jurisdiction except on review of final decisions after an administrative hearing, and then only on a substantial evidence basis. Again, Lahey's argument is misplaced; these statutes do not purport to limit the government's

ability to bring a claim against Medicare providers under a different grant of jurisdiction. "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others." Verizon Md., Inc. v. PSC, 535 U.S. 635, 644, 152 L. Ed. 2d 871, 122 S. Ct. 1753 (2000). In Verizon, the Court concluded that the Congress did not strip the general grant of federal question jurisdiction in 28 U.S.C. § 1331 when it provided for federal review of state commission determinations under a specific provision of the Telecommunications Act. See id. Similarly, the fact that Congress has provided a limited avenue for judicial review in some circumstances does not support an implication that other avenues of judicial review are precluded. n15

Before addressing Lahey's contention that the Medicare Act displaces the United States' common law causes of action, we add a few words about special problems raised by the claim. First, it does not go to subject matter jurisdiction at all. The Supreme Court has stated that "it is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case." Verizon, 535 U.S. at 642-43 (quoting Steel Co. v. Citizens for Better Environment, 523 U.S. 83, 89, 140 L. Ed. 2d 210, 118 S. Ct. 1003 (1998)).

Jurisdiction . . . is not defeated . . . by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. Rather, the district court has jurisdiction if the right of the petitioners to recover under their complaint will be

sustained if the Constitution and laws of the United States are given one construction and will be defeated if they are given another, unless the claim clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or where such a claim is wholly insubstantial and frivolous.

Steel Co., 523 U.S. at 89 (internal quotations and citations omitted). There is no allegation that the United States' claim is "wholly insubstantial and frivolous."

Regardless, Lahey's argument, even if viewed as an argument for failure to state a claim, is simply wrong: the Medicare Act does not displace the common law remedies asserted by the United States. Lahey relies on City of Milwaukee for the proposition that "when Congress addresses a question previously governed by a decision rested on federal common law the need for such an unusual exercise of lawmaking by federal courts disappears." City of Milwaukee, 451 U.S. at 314. Lahey contends that the Medicare Act is a "comprehensive scheme" enacted by Congress that "directly addresses" the United States' remedy for collecting overpayments, and therefore the need for the common law remedy "disappears."

The Court in a subsequent decision, United States v. Texas, recognized that although Congress need not "affirmatively proscribe" the common law doctrine at issue, 507 U.S. at 534 (quoting City of Milwaukee, 451 U.S. at 315), nonetheless "statutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles . . . ." Id. (quoting Isbrandtsen Co. v.

Johnson, 343 U.S. 779, 783, 96 L. Ed. 1294, 72 S. Ct. 1011 (1952)).

This presumption may be even stronger when a longstanding power of the United States is involved. In the context of recovery of overpayments, the government has broad power to recover monies wrongly paid from the Treasury, even absent any express statutory authorization to sue. See United States v. Wurts, 303 U.S. 414, 82 L. Ed. 932, 58 S. Ct. 637 (1938). "The Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. 'No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute . . . .'" Id. at 415 (quoting United States v. Bank of Metropolis, 40 U.S. 377, 15 Pet. 377, 401, 10 L. Ed. 774 (1841)). n16

Congress, of course, by statute can curtail the government's right to sue; however, "courts may take it as a given that Congress has legislated with an expectation that the [common law] principle will apply except 'when a statutory purpose to the contrary is evident.'" Texas, 507 U.S. at 534 (quoting Astoria Fed. Sav. & Loan Ass'n. v. Solimino, 501 U.S. 104, 108, 115 L. Ed. 2d 96, 111 S. Ct. 2166 (1991)). Statutes are presumed not to divest the United States of pre-existing rights, such as the ability to collect wrongfully paid monies, absent a clear congressional command. See United States v. United Mine Workers of America, 330 U.S. 258, 272, 91 L. Ed. 884, 67 S. Ct. 677 (1947)("There is an old and well-known rule that statutes which in general terms divest pre-existing rights or privileges will not be applied to the sovereign without express words to that effect.").

Although provisions of the Medicare Act expressly authorize the Secretary to reopen initial payment determinations and to recoup overpayments administratively in certain circumstances, see 42 U.S.C. § 1395g(a) and 1395gg, the statute does not displace the United States' long standing power to collect monies wrongfully paid through an action independent of the administrative scheme, n17 nor is there any inconsistency. To the extent that a congressional purpose and intent to collect money wrongfully paid by the Medicare program is expressed through the Medicare statutes allowing the Secretary to collect these overpayments, allowing the United States to pursue collection independently is fully consistent with this purpose.

Indeed, the Secretary's very choice of how to proceed illustrates that the administrative remedies are not exclusive when the United States institutes suit. First, the Secretary chose to allow for only particular remedies in the administrative scheme, an indication that the administrative scheme is not exclusive of other remedies elsewhere. Second, the plaintiff in this case is "the United States of America, acting through the Department of Health and Human Services," which reflects the Secretary's position that the common law remedy and federal court jurisdiction under § 1345 are also available. Third, if the administrative remedy were exclusive, that would, in some situations, hinder or preclude the United States from recovering overpayment.

The Secretary has chosen the administrative remedies of suspension, recoupment, and offset (also called a setoff). See 42 C.F.R. §§ 405.370, 405.371. These are

terms of art; "the pertinent distinction between a setoff and a recoupment is whether the debt owed the creditor . . . arose out of the 'same transaction' as the debt the creditor owes the debtor." See Holyoke Nursing Home, Inc. v. Health Care Financing Admin. (In re Holyoke Nursing Home, Inc.), 372 F.3d 1, 3 (1st Cir. 2004). The Secretary's regulations specifically define the types of remedies available to the Secretary for recovering overpayments administratively. An "Offset" is defined as "the recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness." 42 C.F.R. § 405.370. The regulation defines a "Recoupment" as "the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness." Id. Finally, a "Suspension of payment" is defined as "the withholding of payment by an intermediary or carrier from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists." Id.

Each of these remedies of recoupment, offset, and suspension assume an ongoing relationship between the Secretary and the provider. In situations in which there is no ongoing Medicare relationship between the Secretary and the provider, such as where the provider has ceased to treat Medicare beneficiaries or has gone out of business, neither recoupment nor offset would provide the United States with an opportunity to recover the overpaid Medicare payments. In addition, in situations in which the government seeks damages in the form of a complete payment from the provider for the Medicare overpayments, the recoupment,

suspension, and offset procedures do not provide for this relief.

Were more needed, we would say other parts of the federal statutory scheme also refute Lahey's "repeal" and "displacement" arguments and demonstrate that the administrative scheme is not exclusive. In fact, Congress in other statutes has provided for the collection of overpayments independent of the scheme set up by the Medicare Act and the Secretary of HHS. In addition to the common law remedies available to the United States under § 1345, Congress has provided the government two other independent methods to recover overpayments. Under 42 U.S.C. § 1320a-7a(a)(1)(A), the Secretary may seek civil money penalties for knowing violations of the Medicare Act. Further, and wholly independent of the Secretary, the Attorney General may seek to recover Medicare payments made on the basis of a false or fraudulent claim. 31 U.S.C. §§ 3729 - 3733. The existence of these other statutes expresses a clear congressional intent to provide several avenues for the United States to recover monies owed to it and not to limit the means of recovery to those promulgated by the Secretary in the Medicare Act.

To its credit, Lahey correctly concedes that if the statute sued on were the False Claims Act, 31 U.S.C. § 3729-3733, rather than § 1345, the district court would have subject matter jurisdiction, admitting that the Medicare scheme does not impliedly repeal the False Claims Act. The difference, Lahey argues, is that § 1345 simply provides jurisdiction for common law actions, while the False Claims Act embodies a congressionally created cause of action. It is hard for us to fathom why Congress would intend to give the government access

to a judicial forum by statute when the overpayment was procured by fraud but to preclude the government from a routine common law damages action for overpayment. n18

Finally, where two different statutory schemes give concurrent jurisdiction to courts "there is no irreconcilability in the existence of concurrent state and federal jurisdiction." Colorado River Water Conservation District, 424 U.S. at 809. That being so, it is hard to understand why concurrent jurisdiction in a court and the discretionary decision by an agency to create a partially overlapping administrative forum would lead to implied repeal of the court's statutory jurisdiction or displacement of the United States' common law remedies.

C. Primary Jurisdiction

Lahey makes a final plea for deference to the Secretary's administrative expertise n19 by arguing that there should be a primary jurisdiction referral. The primary jurisdiction referral request, denied by the district court, invokes prudential doctrines, and "does not implicate the subject matter jurisdiction of the federal court." See P.R. Mar. Shipping Auth. v. Fed. Mar. Comm'n, 75 F.3d 63, 67 (1st Cir. 1996). It is not within the scope of the certified question to us. Even if we arguably had some form of supplemental appellate jurisdiction to reach the question, we see no basis on which to upset the district court's order.

III.

Conclusion

We affirm the judgment of the district court. Costs are awarded to the United States.

Footnotes

n1 The Health Care Financing Administration is now referred to as the Center for Medicare and Medicaid Services.

n2 Lahey does assert in its statement of facts and in its reply brief that the Medicare statute limits the Secretary's authority to seek restitution of overpayments more than three years after determination of the initial claim. Lahey relies on 42 U.S.C. § 1395gg(b) for the proposition that no collection may be had from a provider who is "without fault," and that the statute presumes that a provider is without fault if the reimbursement determination is more than three years' old. The United States disputes this assertion and offers a different interpretation of the statute. The United States argues that the statute's three-year presumption of "without fault" is limited by the language, "in the absence of evidence to the contrary." Id. This claim does not go to the subject matter jurisdiction of the district court, and therefore we do not address it.

n3 28 U.S.C. § 1345 grants broad jurisdictional power to the district courts over suits when the United States is plaintiff.

n4 Indeed there is a conflict of views within the district of Massachusetts. Compare United States v. Univ. of Mass. Mem'l Med. Ctr., 296 F. Supp. 2d. 20 (D.Mass. 2003) (finding that § 405(h) barred an exercise of subject matter jurisdiction and dismissing the action), with United States v. Lahey Clinic Hosp., 2004 U.S. Dist. LEXIS 7572, No. 03-10194-RWZ (D. Mass. April 30, 2004) (finding that § 405(h) did not apply when the action was brought by the United States). Our opinion today overrules the reasoning in Univ. of Mass. Mem'l Med. Ctr., supra.

n5 This argument does not implicate the district court's subject matter jurisdiction under 12(b)(1) and is beyond the scope of this interlocutory appeal.

n6 "A motion to dismiss an action under Rule 12(b)(1) . . . raises the fundamental question whether the federal district court has subject matter jurisdiction over the action before it." 5B Charles Alan Wright & Arthur B. Miller, Federal Practice and Procedure § 1350, at 61 (3d ed. 2004). While this challenge is usually employed in the instance in which the moving party believes there is no federal question jurisdiction under 28 U.S.C. § 1331 or diversity of citizenship jurisdiction under 28 U.S.C. § 1332, "the scope of Rule 12(b)(1) is flexible," and it can serve as "a procedural vehicle" for raising a variety of challenges to the court's power to hear the case. Id. at 100-02. Failure to exhaust administrative remedies and ripeness challenges may be appropriate in a motion to dismiss for lack of subject matter jurisdiction. See Bonilla v. Muebles J.J. Alvarez, Inc., 194 F.3d 275 (1st Cir. 1999); Deniz v. Municipality of Guaynabo, 285 F.3d 142 (1st Cir. 2002). In addition, jurisdictional facts might be relevant for determining whether the district

court has subject matter jurisdiction in a Rule 12(b)(1) motion when there is a dispute over those facts. See Skwira v. United States, 344 F.3d 64 (1st Cir. 2003) (discussing the different standard of review of the district court's findings as to jurisdictional facts and the district court's ultimate conclusion of subject matter jurisdiction, which is a question of law subject to de novo review). There are, however, no relevant jurisdictional facts in dispute here as the issue is one of law.

n7 Lahey argues that the Supreme Court reasoned in Weinberger v. Salfi, 422 U.S. 749, 766, 45 L. Ed. 2d 522, 95 S. Ct. 2457 (1975), that the federal courts do not have jurisdiction over claims involving Medicare overpayment decisions, until the two jurisdictional prerequisites of § 405(h) -- initial presentment to the Secretary and administrative exhaustion through the agency's administrative review and hearing procedures -- are satisfied. We disagree with Lahey's reading of Salfi as it relates to this case for two reasons. First, Salfi involved a constitutional challenge by a class of individuals who brought an action against the Secretary seeking to recover Social Security benefits. Id. at 755. Second, the United States does not rely on the Medicare Act as the source of its cause of action or the jurisdictional basis of its claim. It relies on 28 U.S.C. § 1345 for jurisdiction and common law remedies to recover payments erroneously made out of the public fisc. Salfi is factually distinct, and the Salfi Court did not engage in an analysis of implied repeal of § 1345 or the displacement of the federal common law claims.

n8 Lahey's argument appears to assume that if the federal courts lack jurisdiction, the United States could

not bring a common law action in state courts. That might be a possible conclusion out of Lahey's second argument (displacement of the common law causes of action), but surely not as to the first (repeal of § 1345).

n9 It is unclear whether implied repeal of a jurisdictional statute, such as § 1345, can be effectuated by the second test articulated in Kremer. Kremer did not deal with a grant of federal court jurisdiction. This court has adopted the reasoning of Kremer as it applies to the implied repeal of § 1345. See United States v. Commonwealth of Puerto Rico, 721 F.2d 832 (1st Cir. 1983). However, there the court limited its repeal analysis to whether § 1345 was irreconcilable with the subsequent statute and determined that it was not. Congress could easily wish to change a substantive rule without depriving the federal courts of jurisdiction.

The second test articulated in Kremer is relevant when dealing with the implied repeal of a rule of law apart from the jurisdiction of the court. However, Colorado River may limit the implied repeal of jurisdictional statutes only to situations where jurisdiction of the federal courts under § 1345 is irreconcilable with the subsequent statute. See Colorado River, 424 U.S. at 808 ("In the absence of some affirmative showing of an intention to repeal, the only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable.") (quoting Morton v. Mancari, 417 U.S. 535, 550, 41 L. Ed. 2d 290, 94 S. Ct. 2474 (1974)).

n10 The text of 405(g) and 405(h) refers to the "Commissioner of Social Security" rather than the Secretary. The statutory provisions applying § 405(h)

to Medicare, however, make clear that references to the Commissioner should be deemed to be references to the "Secretary" where the context indicates. See 42 U.S.C. § 1395ii.

n11 Lahey's brief also directs the court's attention to the Federal Claims Collection Act, 31 U.S.C. § 3711(a)(1). In this statute, Congress mandated that heads of agencies attempt to recover overpayments. The statute provides in pertinent part:

§ 3711. Collection and compromise

(a) The head of an executive, judicial, or legislative agency - -

(1) shall try to collect a claim of the United States Government for money or property arising out of the activities of, or referred to, the agency . . . .

31 U.S.C. § 3711(a)(1). Quite correctly Lahey does not suggest that this statute somehow expresses a congressional intent to preclude the United States from pursuing overpayment actions under § 1345 or displaces the federal common law remedies available to the United States.

n12 Subsequent case law suggests that resort to legislative history is more appropriate in the implied repeal analysis. See Kremer, 456 U.S. 461, 72 L. Ed. 2d 262, 102 S. Ct. 1883 (examining legislative history to determine whether a previous statute had been implicitly repealed by a subsequent statute); Commonwealth of Puerto Rico, 721 F.2d 832 (examining legislative history to determine whether

Congress impliedly repealed § 1345); Kenaan, 557 F.2d at 916. Regardless of under which prong of the repeal analysis legislative history is considered, the legislative history relevant to Lahey's claims does not advance Lahey's argument that § 1345 was repealed by the Medicare Act.

n13 As to reimbursement determinations made after October 1, 2002, an amendment, which was enacted in October 2000 and is not relevant to the claims at issue in this case, provides:

(G) Reopening and Revision of Determinations.

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

42 U.S.C. § 1395ff(b)(1)(G). It expresses no intent by Congress to displace the federal common law or repeal federal jurisdiction under § 1345, by making this the exclusive avenue for reopening or revisiting initial payment determinations. Indeed the language of the statute itself suggests that the Secretary is not required to reopen or revise initial determinations. Surely Congress would not limit the ability to the government to bring an action outside of the administrative scheme yet not require the Secretary to collect overpayments.

n14 Section 1395oo creates the Provider Reimbursement Review Board which is charged with holding hearings and rendering decisions in disputes over Part A payments. The claims in this case involve

payments under Part B of Medicare. Additionally, § 1395oo by its terms provides for administrative and judicial review of claims filed by providers.

n15 In addition, Lahey reads the judicial review provisions of the Medicare Act out of context. Section 1395ff(b), during the time relevant to this appeal, provided that "any individual dissatisfied with any determination under subsection (a) of this section as to . . . the amount of benefits . . . shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in § 405(b) of this title and to judicial review of the Secretary's final decisions after such hearing as is provided in § 405(g) of this title." After the individual or provider has exhausted the administrative provisions laid out in § 405(b), the individual is then allowed to seek judicial review under § 405(g). The United States' ability to bring claims against the providers is not implicated at all in the provisions relating to how to challenge the FI's payment decisions. It is this administrative mechanism, as it relates to claims by providers, that § 405(h) makes the exclusive avenue of judicial review.

n16 United States v. Wurts and the cases it relies on do not refer to the government's power to collect money wrongfully paid as a construction of the common law. See 303 U.S. 414, 82 L. Ed. 932, 58 S. Ct. 637 (1938). Indeed, the power of the United States to recover sums illegally or erroneously paid has been described by one court as part of the United States' "inherent authority." Aetna Cas. & Sur. Co. v. United States, 208 Ct. Cl. 515, 526 F.2d 1127, 1130 (Ct. Claims 1975). The Court of Claims suggested that an erroneously or illegally made payment is tied to a direct violation of the United

States Constitution, Article IV, section 3, clause 2, id., which lodges with the Congress the power to "release or otherwise dispose of the rights and property of the United States." See Royal Indemnity Co. v. United States, 313 U.S. 289, 294, 85 L. Ed. 1361, 61 S. Ct. 995 (1941). The causes of action asserted here for exercising this right are common law causes of action, but the right itself seems to be something more intimately tied with the power of the United States.

n17 The fact that the Medicare Act will be relevant to the common law action does not mean it displaces suit by the United States. In order to prove the allegations in the complaint, that indeed the payments were wrongfully made, the United States will have to refer to Medicare manuals, regulations, and other materials that relate to the appropriateness of the previous payments. However they in no way displace or limit the underlying ability to bring the independent claim for recovery. "Congress's obvious desire to enhance the common law in specific, well-defined situations does not signal its desire to extinguish the common law in other situations." Texas, 507 U.S. at 535 n.4.

n18 Lahey also argues that there is a meaningful difference for these purposes between actions for fraud and actions for recovery which do not assert fraud, as under § 1345. Lahey argues the court is particularly well equipped to handle cases involving fraud as opposed to cases involving unjust enrichment and payment under mistake of fact, which implicate the expertise of the agency. We do not see a meaningful distinction: a False Claims Act action would involve the same interpretation of Medicare codes as an overpayment action with the largest difference being

that the government under the False Claims Act must also show fraudulent intent.

n19 Lahey also asserts a parade of horribles argument: that the case is too complex to be tried in federal court, that the problems of proof of overpayment of numerous claims are insurmountable, and that the case would take twenty years to try. One response is that these cases are less complicated to try than fraud cases, which Lahey concedes are permissible. Further, sampling of similar claims and extrapolation from the sample is a recognized method of proof. Chaves County Home Health Serv., Inc. v. Sullivan, 289 U.S. App. D.C. 276, 931 F.2d 914, 919 (D.C. Cir. 1991); Ratasen v. Cal. Dept. of Health Servs., 11 F.3d 1467, 1471 (9th Cir. 1993). There is no reason to doubt the competence of courts; both civil and criminal cases for abuse of the Medicare system by providers are sadly common. See, e.g., United States v. McGovern, 329 F.3d 247 (1st Cir. 2003).

CIVIL ACTION NO. 03-10194-RWZ

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES

v.

LAHEY CLINIC HOSPITAL

April 30, 2004, Decided

COUNSEL: For USA, Plaintiff: Nancy Rue, LEAD ATTORNEY, United States Attorney's Office, Boston, MA.

For Lahey Clinic, Defendant: Richard P. Ward, LEAD ATTORNEY, Ropes & Gray LLP, Boston, MA.

JUDGES: RYA W. ZOBEL, UNITED STATES DISTRICT JUDGE.

OPINION BY: RYA W. ZOBEL

OPINION:

MEMORANDUM OF DECISION

ZOBEL, D.J.

Plaintiff United States, acting through the Department of Health and Human Services ("HHS"), administers and supervises the Health Insurance for the Aged and Disabled Program, under Title XVIII of the Social

Security Act, 42 U.S.C. § 1395, et seq., otherwise known as the Medicare Program ("Medicare"). During the relevant time period, the Health Care Financing Administration ("HCFA"), a component of HHS, was directly responsible for administering the Medicare Program. Defendant Lahey Clinic Hospital entered into a provider agreement with plaintiff, which allowed it to be reimbursed by Medicare through Blue Cross Blue Shield in Massachusetts. For reimbursement purposes, Medicare follows HCFA's three level Common Procedure Coding System ("HCPCS"). For Level One (the only level relevant here), HCPCS adopts the American Medical Association Physicians' Current Procedure Terminology (CPT) coding system in the CPT-4 Manual. Generally, costs for medical services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" are not reimbursable. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

Plaintiff contends that defendant billed it for one to three additional unnecessary hemogram indices (CPT-4 code 85029) every time it billed for a complete blood count ("CBC") (CPT-4 code 85023 or 85027) from 1993 through 1996. (Compl. at 11). These additional indices were automatically generated whenever the automated blood analyzer used by defendant processed a CBC. (Compl. at 11). Defendant billed for the CBC and then separately billed for the additional indices, which, according to plaintiff, violates the Medicare Act because they are rarely medically necessary, and they should be specifically ordered by a physician. As a result of defendant's billing procedure, Medicare paid an additional $ 225,000 for the over 88,000 claims

submitted to it between July 1, 1993 through December 31, 1996.

Plaintiff also asserts that Medicare requires that specific blood chemistry tests be bundled together and billed as a single blood chemistry profile if the tests are for the same person, on the same day, and from the same blood sample. The CPT-4 codes generally associate chemistry profiles with the number of individual tests performed. The codes correspond to the number of individual tests to be run because it is more economical for plaintiff to reimburse defendant for the cost of running a battery of tests rather than each individual test. Instead of bundling its automated blood chemistry profiles, plaintiff contends that defendant broke down larger profiles into smaller, component profiles and billed for them separately. Defendant thereby increased its reimbursement by $ 86,000 for the profiles submitted between July 1, 1993 through June 30, 1994, covering over 9,300 Medicare claims.

Plaintiff seeks to recoup its overpayments on the theory that it paid under mistake of fact and defendant was unjustly enriched. Defendant moves for judgment on the pleadings or in the alternative, for summary judgment, on the following grounds: (1) lack of subject matter jurisdiction, (2) failure to exhaust administrative remedies and issues of ripeness, (3) lack of officially promulgated regulations prohibiting defendant's billing practice, and (4) adequate remedies in law that bar plaintiff's equitable claims. n1 Relying on 42 U.S.C. § 405(h), defendant argues that no subject matter jurisdiction exists. Section 405(h) states that:

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). More specifically, defendant contends that HHS must exhaust its administrative remedies before seeking judicial review.

The parties agree that "Section 405(h) purports to make exclusive the judicial review method set forth in § 405(g)." Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 10, 120 S. Ct. 1084, 1091, 146 L. Ed. 2d 1 (2000); Heckler v. Ringer, 466 U.S. 602, 614-5, 104 S. Ct. 2013, 2021, 80 L. Ed. 2d 622 (1984) (stating that the third sentence of Section 405(h) makes Section 405(g) the "sole avenue for judicial review."). As are all the cases cited by defendant, Section 405(g) is inapposite.n2

Section 405(g) states that "any individual" may bring suit in district court after a final decision by the Secretary and requires that "as part of the [Secretary's] answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based." 42 U.S.C. § 405(g). Section 405(g) clearly contemplates administrative exhaustion in cases against the Secretary--not cases by the Secretary. This reading is further supported by United States v. Aquavella, 615 F.2d 12 (2d Cir. 1980), where

the government sought to recover alleged overpayments made to a nursing home under the Medicare Act. The Second Circuit concluded that "§ 405(h) was not intended to preclude the district court from considering the merits of the government's claims of overpayment or [the provider's] defense by way of offset" because "§ 405(h) by its terms applies only to actions brought against the government and not by the government [and] to hold otherwise would totally deprive [the providers] of any judicial review." Id. at 20, 21.

Finally, the policy reasons for requiring administrative exhaustion do not apply when the government is the plaintiff. "Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." Weinberger v. Salfi, 422 U.S. 749, 765, 95 S. Ct. 2457, 2467, 45 L. Ed. 2d 522 (1975); Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13, 120 S. Ct. 1084, 1093, 146 L. Ed. 2d 1 (2000) ("insofar as [Section 405(h)] demands the 'channeling' of virtually all legal attacks through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by difference individual courts ...."). However, "once a benefit applicant has presented his or her claim at a sufficiently high level of review to satisfy the Secretary's administrative needs, further exhaustion would not merely be futile for the applicant, but would also be a commitment of administrative

resources unsupported by any administrative or judicial interest." Weinberger v. Salfi, 422 U.S. 749, 765, 95 S. Ct. 2457, 2467, 45 L. Ed. 2d 522 (1975). Furthermore, the term "final decision" is undefined by the Social Security Act and the "statutory scheme is thus one in which the Secretary may specify such requirements for exhaustion as he deems serve his own interests in effective and efficient administration." Id. Therefore, it would be inconsistent with the scheme "to bar the Secretary from determining in particular cases that full exhaustion of internal review procedures is not necessary for a decision to be 'final' within the language of § 405(g)." Id. For these reasons, defendant's arguments concerning subject matter jurisdiction, the necessity of administrative exhaustion, and the doctrine of ripeness fail. The Court properly has jurisdiction. n3

The parties hotly dispute whether defendant's billing practices were proper and whether plaintiff's claims are enforceable. Apart from the legal questions, there are serious contested issues of fact, and the record here is particularly confusing because the parties refer to outside documents without explaining their meaning, import, and weight of authority. Therefore, on this record, summary judgment is denied.

Accordingly, defendant's motion for summary judgment is denied.

The Court is of the opinion that this Order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from this Order may materially advance the ultimate termination of the litigation.

April 30, 2004
DATE

/s/
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

Footnotes

n1 Although the papers were filed before discovery had begun, the parties have had ample opportunity to present pertinent material. Therefore, the Court will treat defendant's motion as a motion for summary judgment.

n2 The cases cited by defendant are distinguishable since none of them involve United States as plaintiff. After the initial papers were filed, defendant brought to the Court's attention one case where the United States was plaintiff, United States v. University of Massachusetts Memorial Medical Center, 296 F. Supp. 2d 20, 2003 WL 22988889 (D. Mass.). I respectfully disagree with the analysis and outcome of the case.

n3 This ruling also dictates the conclusion that defendant's fourth contention is unavailing. Defendant argued that equitable claims are barred because the Medicare statutory and regulatory scheme provide adequate remedies.

CIVIL ACTION NO. 03-10195-WGY

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES,
Plaintiff,

v.

UNIVERSITY OF MASSACHUSETTS
MEMORIAL MEDICAL CENTER,
Defendant.

December 19, 2003, Decided

COUNSEL: For USA, Plaintiff: Nancy Rue, LEAD ATTORNEY, United States Attorney's Office, Boston, MA.

For University Of Massachusetts Memorial Medical Center, Defendant: Richard P. Ward, LEAD ATTORNEY, Ropes & Gray LLP, Boston, MA.

JUDGES: WILLIAM G. YOUNG, CHIEF JUDGE.

OPINIONBY: WILLIAM G. YOUNG

OPINION:

MEMORANDUM AND ORDER

YOUNG, C.J.
The United States alleges that the defendant, the University of Massachusetts Medical Memorial Center

("UMass"), improperly received overpayments for outpatient laboratory services provided to Medicare beneficiaries. Seeking to recoup those overpayments, the United States initiated the present suit, asserting common law causes of action for unjust enrichment and payment under mistake of fact, and requesting various equitable remedies including an accounting, disgorgement of improper gains, imposition of a constructive trust, and prejudgment interest. UMass moved to dismiss for lack of subject matter jurisdiction.

I. PROCEDURAL AND REGULATORY BACKGROUND n1

The United States alleges that UMass, in providing and billing for Medicare services, has submitted claims resulting in systematic overpayment. Compl. [Doc. No. 1] PP 66, 71, 74, 75, 81. The specific claims at issue are those submitted for complete blood counts and for blood chemistry tests performed on an outpatient basis between July 1, 1993, and December 31, 1996. Id. PP 66, 75. While the parties dispute precisely how these claims were reimbursed, they agree that the Department of Health and Human Services ("HHS"), the agency charged with administering the Medicare program, determined and paid out the reimbursements, and that UMass received them. Id. PP 75, 86; Def.'s Reply Br. [Doc. No. 14] at 2.

As the United States stated at oral argument on September 11, 2003, its Complaint reflects the findings of a nationwide investigation of Medicare billing conducted by the Department of Justice. Having removed the inquiry from HHS, the United States argues that it is neither appropriate nor necessary to

return the matter to the agency to exhaust administrative procedures. See Pl.'s Opp'n [Doc. No. 12] at 10-12 (arguing, inter alia, that "this is because [administrative] remedies are simply inapplicable to claims brought by the United States," and that "from a factual standpoint, no administrative process is appropriate because the United States' allegations in this case are very simple.").

Citing the United States' failure to exhaust, UMass seeks dismissal or judgment on the pleadings based on a lack of subject matter jurisdiction, on considerations of justiciability, and on the adequacy of legal remedies. Def.'s Mot. to Dismiss. [Doc. No. 9]; Def.'s Mem. in Support [Doc. No. 10] at 1. The Court begins, as it must, by considering its subject matter jurisdiction.

II. DISCUSSION

A. Legal Standard

On a motion to dismiss under Rule 12(b)(1), "the party invoking federal court jurisdiction bears the burden of proving its existence." Pejepscot Indus. Park, Inc. v. Maine Cent. R.R. Co., 215 F.3d 195, 200 (1st Cir. 2000). Proper construction of the complaint depends on the nature of the movant's challenge. See Valentin v. Hospital Bella Vista, 254 F.3d 358, 363 (1st Cir. 2001). If the challenge is to the sufficiency of the facts supporting jurisdiction, the Court should credit the plaintiff's well-pleaded factual allegations as true and draw all reasonable inferences from them in his favor. Id. If, however, the challenge is to the accuracy of the facts supporting jurisdiction, "the plaintiff's jurisdictional averments are entitled to no presumptive

weight; the court must address the merits of the jurisdictional claim by resolving the factual disputes between the parties." Id.

Here, UMass challenges the accuracy of the facts supporting jurisdiction, urging the Court to "determine the relevant actual facts" rather than credit the allegations in the United States' Complaint. Def.'s Mot. to Dismiss at 1. The Court accordingly enjoys "considerable leeway" in deciding any "factbound jurisdictional question[s]." Valentin, 254 F.3d at 364. The Court must weigh the proof and draw reasonable inferences to satisfy itself that subject matter jurisdiction exists. Id.

B. 42 U.S.C. § 405(h)

UMass asserts that Section 405(h) bars an exercise of subject matter jurisdiction over the present action, which seeks review of the Secretary's reimbursement determinations prior to administrative exhaustion. Def.'s Mem. in Support at 7-11. In response, the United States contends that the jurisdictional limits imposed by Section 405(h) apply to actions brought against the United States only. Pl.'s Opp'n at 6-10. In support of this interpretation, the United States contends, inter alia, that requiring it to exhaust the administrative process would be inappropriate and unnecessary. Pl.'s Opp'n at 10-12. The threshold question whether the limits imposed by Section 405(h) apply to actions brought by the United States appears to be one of first impression in this Circuit. n2

Before proceeding, the Court emphasizes that this Memorandum does not concern an action brought under

the False Claims Act. See 31 U.S.C. § § 3729-33 (2000). Actions brought under the False Claims Act do not fall within the special competence of HHS. Rather, actions brought under the "expansively" written False Claims Act seek "to reach all types of fraud," committed on all types of agencies. Cook County v. United States ex rel. Chandler, 538 U.S. 119, 123 S. Ct. 1239, 1246, 155 L. Ed. 2d 247 (2003) (quoting United States v. Neifert-White Co., 390 U.S. 228, 232, 19 L. Ed. 2d 1061, 88 S. Ct. 959 (1968)). Moreover, claims alleging fraud and falsity fall "within the conventional experience of judges." In re Long Distance Telecomm. Litig., 831 F.2d 627, 633 (6th Cir. 1987) (quoting Far East Conf. v. United States, 342 U.S. 570, 574, 96 L. Ed. 576, 72 S. Ct. 492 (1952)).

Here, however, the United States seeks to recover overpayments due not to fraud or falsity but to misinterpretation of Medicare regulations. The United States' claims are accordingly "inextricably intertwined" with reimbursement determinations that are the subject of the Secretary's particular experience and expertise. See Heckler v. Ringer, 466 U.S. 602, 614, 80 L. Ed. 2d 622, 104 S. Ct. 2013 (1984); 42 U.S.C. § 1395g ("The Secretary shall periodically determine the amount which should be paid under this part to each provider of services ...."). Because Section 405(h) has been interpreted to assure the Secretary "greater opportunity to apply, interpret, or revise policies, regulations, or statutes," the provision assumes special significance in the present action. Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13, 146 L. Ed. 2d 1, 120 S. Ct. 1084 (2000).

In construing Section 405(h) as it applies here, the Court follows the "familiar canon of statutory

construction that the starting point for interpreting a statute is the language of the statute itself." Consumer Prod. Safety Comm'n v. GTE, Sylvania, Inc., 447 U.S. 102, 108, 64 L. Ed. 2d 766, 100 S. Ct. 2051 (1980). Section 405 (h), as applied to the Medicare Act, provides:

Finality of [Secretary's] decision

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h), as applied by 42 U.S.C. § 1395ii.

The second sentence of Section 405 (h) provides that "no findings of fact or decision of the [Secretary] shall be reviewed ... except as herein provided." 42 U.S.C. § 405 (h). No part of the sentence suggests that review is limited only in actions brought against the United States. Cf. Weinberger v. Salfi, 422 U.S. 749, 757, 45 L. Ed. 2d 522, 95 S. Ct. 2457 (1975) (rejecting a narrow interpretation of Section 405 (h) as inconsistent with the "sweeping and direct" language of the provision's third sentence). Indeed, if application of the second sentence were limited to actions brought against the United States, it would be largely superfluous because actions "against the United States, the Secretary, or any officer of employee thereof" are independently barred by the third sentence. Cf. id. at 758 (rejecting an

interpretation that relegated the third sentence of Section 405(h) "to a function which is already performed by other statutory provisions").

This Court's reading of Section 405 (h) is supported by previous constructions by the Supreme Court and by other lower courts. In Salfi, the Supreme Court concluded that the third sentence of Section 405(h), if properly construed to have independent significance, extended beyond "a codified requirement of administrative exhaustion." Id. at 758. The Supreme Court's conclusion was based in part on its interpretation of the first two sentences of Section 405(h). Id. at 757-59. The Supreme Court noted that those sentences, wholly apart from the third sentence, "assure that administrative exhaustion will be required" and more specifically, "prevent review of decisions of the Secretary save as provided in the Act." Id. at 758. In a footnote, n3 the Supreme Court explained that "by virtue of the second sentence," even a "nonfinal" determination by the Secretary "may not be reviewed save pursuant to § 405(g)." n4 Id. at 759 n.6.

Consistently with Salfi, the United States District Court for the District of Idaho concluded that Section 405(h) "does not merely apply to actions brought against the government to recover benefits under the Medicare Act." United States v. Idaho Falls Assocs. Ltd. Partnership, 81 F. Supp. 2d 1033, 1049 (D. Idaho 1999). The court in Idaho Falls focused on the second sentence of the provision, which "makes clear that a court is precluded from undertaking judicial review of any findings of fact or decisions of the Secretary except as provided in the Medicare Act itself." Id. Accordingly,

the court concluded that Section 405(h) applied to an action brought by the United States against a Medicare provider and barred jurisdiction over the provider's defense to liability. Id. at 1049, 1051. Although Idaho Falls interpreted Section 405(h) to bar consideration of the defendant's rather than the plaintiff's claims, it applied the provision in the same context as that presented here, in which the United States has brought suit to recover alleged overpayments. Id. at 1036. Idaho Falls and Salfi thus suggest that the second sentence of Section 405(h) bars jurisdiction over this action. n5

The United States nevertheless argues that the third sentence of Section 405(h), which refers only to actions brought against the United States under 28 U.S.C. § § 1331 or 1346, "manifests Congress' intent that actions brought by the United States [under 28 U.S.C. § 1345] are excluded from its scope." Pl.'s Opp'n at 7. As an initial matter, the Court notes that its interpretation of Section 405(h) rests largely on the second sentence of the provision rather than the third. Perhaps, then, the United States' argument should be read as urging an interpretation of the second sentence that considers the context provided by the third. Yet the context of the surrounding sentences provides further support for the Court's interpretation. As stated above, because the third sentence of Section 405(h) independently bars jurisdiction over actions brought against the United States, limiting application of the second sentence to very same actions would render it largely "superfluous." Cf. Salfi, 422 U.S. at 758 (rejecting an interpretation of the third sentence of Section 405(h) which not only "ignored that sentence's plain language," but also "relegated it to a function which is already performed by other statutory provisions").

The United States responds with several cases that it believes suggest that Section 405(h) does not require the United States to exhaust administrative remedies when it is the plaintiff. Pl.'s Opp'n at 9. These cases, however, are distinguishable. United States ex. rel. Body v. Blue Cross and Blue Shield of Alabama, Inc., 156 F.3d 1098 (11th Cir. 1998), for example, n6 considered whether Section 405(h) barred jurisdiction over an action brought under the False Claims Act, an issue that, as emphasized above, is not before this Court. Moreover, the Body court based its decision in part on the belief that its interpretation was "further confirm[ed]" by Supreme Court case law, and in particular, was "perhaps most clearly" supported by Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 90 L. Ed. 2d 623, 106 S. Ct. 2133 (1986). Body, 156 F.3d at 1104, 1109. The panel read Michigan Academy as demonstrating that Section 405(h) "simply seeks to preserve the integrity of the administrative process Congress designed to deal with challenges to amounts determinations by dissatisfied beneficiaries." Id. at 1109. Yet the Supreme Court has since clarified its holding in Michigan Academy, explaining that the words of the opinion "do not limit the scope of 405(h) itself to instances where a plaintiff, invoking § 1331, seeks review of an 'amount determination.'" Illinois Council, 529 U.S. at 17. n7 The Supreme Court considered it "more plausible" to read Michigan Academy as holding that Section 405(h) does not apply "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Id. at 19. This exception to Section 405 (h) is inapplicable here, as the agency has clearly established procedures to review and to redress overpayments to providers. See National Kidney

Patients Association, 958 F.2d at 1137. The fact that the United States apparently may not obtain review absent a determination of overpayment by an intermediary, a carrier, or HHS does not alter the analysis. Cf. Your Home Visiting Nurse Servs. v. Shalala, 525 U.S. 449, 142 L. Ed. 2d 919, 119 S. Ct. 930 (1999) (concluding that a Medicare provider may not obtain review of an intermediary's refusal to reopen a notice of program reimbursement).

In further support of its interpretation, the United States argues that requiring it to exhaust would be "inappropriate and unnecessary." Pl.'s Opp'n at 10-12. First, the United States asserts, based on Salfi, that "administrative exhaustion is not appropriate when the action is brought on behalf of the Secretary rather than on behalf of a claimant." Pl.'s Opp'n at 8. This reliance on Salfi, however, is misplaced. The Secretary in Salfi, as a party to the action, had not challenged the appellees' allegations of exhaustion. Salfi, 422 U.S. at 767. The Supreme Court interpreted this "to be a determination by him that ... the reconsideration determination is 'final.'" Id. The United States has not, either in its written or oral arguments, presented facts upon which this Court could base a similar determination. Indeed, at oral argument, the United States reported that the overpayment determination had been made by the Department of Justice independently of the Secretary. Accordingly, acting within its "considerable leeway" to resolve factual disputes regarding its jurisdiction, Valentin, 254 F.3d at 362, this Court interprets the United States' omissions and assertions as conceding that it has not exhausted agency procedures.

Second, the United States contends that barring judicial review of the present claims would be "inconsistent with, and nonsensical under" the following Medicare regulations:

(c) Amount of claim. [Center for Medicare and Medicaid Services] refers all claims that exceed $ 100,000 ... to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(f) Fraud. The regulations in this subpart do not apply to claims in which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of a debtor or any other party having an interest in the claim. [Center for Medicare and Medicaid Services] forwards these claims to the Department of Justice for disposition under 4 C.F.R. § 105.1.

42 C.F.R. § 401.601 (c), (f); Pl.'s Opp'n at 10. The United States argues that if Section 405(h) is broadly construed to bar review of all claims absent administrative exhaustion, the government "would be effectively foreclosed from collecting" claims exceeding $ 100,000 or indicating fraud, falsity, or misrepresentation, claims for which the above regulations have limited agency review. Id.

While the United States' concerns are legitimate, they are wide of the mark, involving actions and claims very different from those raised here. The claims described in 42 C.F.R. § 401.601 (c) are referred to the Department of Justice or General Accounting Office for compromise, suspension, or termination only. Because

courts reviewing those actions are not called upon to determine the appropriate amount due, they are less directly involved in interpreting the "hundreds of pages of statutes and thousands of pages of often interrelated regulations" that are the subject of the Secretary's expertise. Illinois Council, 529 U.S. at 13. Here, however, the United States asks the Court to "determine whether UMass billing practices comported with Medicare requirements." Pl.'s Opp'n at 13. The United States claims are in this way "inextricably intertwined" with Medicare's complex statutory and regulatory scheme, which entrusts reimbursement determinations, at least initially, to the Secretary. See Ringer, 466 U.S. at 611.

The claims described in 42 C.F.R. § 401.601(f), which indicate fraud, falsity, or misrepresentation, are also distinguishable. Because such claims "fall within the conventional experience of judges," they "do not require agency expertise for their treatment." Long Distance Telecomm. Litig., 831 F.2d at 633 (quoting Far East Conference, 342 U.S. at 574); see Mashpee Tribe v. New Seabury Corp., 592 F.2d 575, 580-81 (1st Cir. 1979) (concluding that the appropriateness of deference to agency expertise depends in part on "whether the agency determination l[ies] at the heart of the task assigned the agency by Congress"). In contrast, even under the United States' simplified version of its allegations, the present claims require interpretations of HHS reimbursement regulations and manuals. In the complex scheme of Medicare reimbursement, the First Circuit has afforded the Secretary "a heightened degree of deference," acknowledging that Congress recognized legislators' and judges' lack of medical expertise and accordingly assigned the Secretary

primary responsibility for "assessing reasonable costs owed to Medicare providers." La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992) (quoting Butler County Memorial Hosp. v. Heckler, 780 F.2d 352, 356 (3d Cir. 1985)). The Court thus considers it appropriate to defer to the Secretary's interpretations and applications of Medicare reimbursement regulations.

In partial response, the United States maintained at oral argument that it would be "administratively inefficient" to remove claims that indicate fraud, falsity, or misrepresentation to the Department of Justice, only to return those claims that do not in fact involve fraud to HHS before permitting judicial review. While this Court does not discount the seriousness of potential inefficiency, it shares the view expressed by the Supreme Court in Illinois Council: the assurance of expertise and uniformity provided by Section 405 (h) "comes at a price." Illinois Council, 529 U.S. at 13. The language of Section 405(h) suggests that in Congress' judgment, paying the price of occasional inefficiency was justified to prevent "possibly premature interference by different individual courts" applying different interpretations of Medicare's complex statute and regulations. Cf. id. (reasoning that it was "the judgment of Congress" that paying the price of "occasional individual, delay-related hardship" was justified in the context of a "massive, complex health and safety program").

Notwithstanding the contrary assertions of the United States, the Court concludes that Section 405(h) bars an exercise of subject matter jurisdiction over this action. Because this issue is dispositive, the Court does not

address UMass' arguments regarding the doctrines of primary and exclusive jurisdiction, considerations of justiciability, or the adequacy of legal remedies.

III. CONCLUSION

For the foregoing reasons, the Defendant's Motion to Dismiss [Doc. No. 9] is ALLOWED.

SO ORDERED.
/s/
WILLIAM G. YOUNG
CHIEF JUDGE

Footnotes

n1 Consistent with the standard for review of a factual challenge to subject matter jurisdiction, the Court draws the following facts primarily from the United States' Complaint, Memorandum in Opposition, and oral argument, but does not afford any presumptive weight to the jurisdictional averments made in those submissions. See section II. A below.

n2 In McCuin v. Secretary of Health & Human Servs., 817 F.2d 161 (1st Cir. 1987), the First Circuit considered the scope of Section 405(h), but with respect to the type of challenge raised rather than the identity of the party raising the challenge. See id. at 166 (concluding that Section 405 (h) bars challenges to the amounts of Medicare determinations but not to the procedures used to make those determinations).

n3 Based in part on this footnote in Salfi, the Court rejects the United States' contention that the phrase "decision of the [Secretary]," as used in the second sentence of Section 405(h), should be interpreted to refer to a "final decision of the [Secretary] made after a hearing," as used in Section 405(g). See Pl.'s Opp'n at 4 & n.2. Salfi expressly interprets Section 405(h) to apply even to "nonfinal decisions." Salfi, 422 U.S. at 759 n.6. Moreover, Congress' use of different phrases in Sections 405(h) and (g) suggests that it intended to convey different meanings. See Pastore v. Medford Sav. Bank, 186 B.R. 553, 555 (D. Mass. 1995) (Lindsay, J.) ("Where Congress has carefully employed a term in one place but excluded it in another, it should not be implied where excluded." (quoting McDermott & Co., Inc. v. Vessel Morning Star, 457 F.2d 815, 818 (5th Cir. 1972)).

n4 As applied to the Medicare Act, Section 405(g) provides, in relevant part:

Judicial review

Any individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the [Secretary] may allow.

42 U.S.C. § 405(g), as applied by 42 U.S.C. § 1395ii.

n5 Although Salfi focused on judicial review available under Section 405(g), the Supreme Court in Illinois Council, 529 U.S. 1, 146 L. Ed. 2d 1, 120 S. Ct. 1084, suggested that the crucial determination is not whether review is available under Section 405(g), but rather whether review is available at all. Id. at 19. The United States does not dispute that review is available under the "administrative process[es]" for recoupment. See Pl.'s Opp'n at 10-12; see also National Kidney Patients Ass'n v. Sullivan, 294 U.S. App. D.C. 269, 958 F.2d 1127, 1137 (D.C. Cir. 1992) ("Under the Medicare legislation HHS has established elaborate procedures for recoupment of overpayments to suppliers.").

n6 The other cases cited by the United States include two decisions that declined to apply Section 405(h) to pre-1973 claims, for which there were no statutory procedures for provider appeals. See United States v. California Care Corp., 709 F.2d 1241 (9th Cir. 1983); United States v. Aquavella, 615 F.2d 12 (2d Cir. 1979). Because Congress amended the Medicare Act in 1972 to provide appeals procedures for provider overpayments, the conclusions reached in California Care and Aquavella are no longer persuasive. See Idaho Falls, 81 F. Supp. 2d at 1049-50.

The United States also cites Klein v. Heckler, 761 F.2d 1304 (9th Cir. 1985). Pl.'s Opp'n at 9. Klein relied upon California Care to support the proposition that the Ninth Circuit "has recognized jurisdiction" over normal recoupment actions. Id. at 1309. California Care, however, made clear that its exercise of jurisdiction extended only to pre-1973 cost reporting years. Id. 709 F.2d at 1246.

n7 For an opinion continuing to rely on Body's reasoning even after the Supreme Court's decision in Illinois Council, see United States v. Rogers, 2001 U.S. Dist. LEXIS 24914, 2001 WL 818160 (E.D. Tenn. June 28, 2001). The context of Rogers, however, appears more closely analogous to that of Body than to that of the present action. In Rogers, as in Body, the suit was brought under the False Claims Act to recover reimbursements for false and fraudulent claims. Rogers, 2001 U.S. Dist. LEXIS 24914, [WL] at *1.

STATUTES

28 U.S.C. Section 1292. Interlocutory decisions

(b) When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order: Provided, however, That application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.

28 U.S.C. Section 1345. United States as plaintiff

Except as otherwise provided by Act of Congress, the district courts shall have original jurisdiction of all civil actions, suits or proceedings commenced by the United States, or by any agency or officer thereof expressly authorized to sue by Act of Congress.

42 U.S.C. Section 405(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing

to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand

the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

42 U.S.C. Section 405(h) Finality of [Secretary's] decision

The findings and decision of the [Secretary or the Department of Health and Human Services] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary or the Department Health and Human

Services] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary or the Department of Health and Human Services] or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. Section 1320c-1. "Utilization and quality control peer review organization" defined

The term "utilization and quality control peer review organization" means an entity which -

(1)(A) is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1320c-2 of this title, with respect to which the entity shall perform services under this part, or (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

42 U.S.C. Section 1320c-3. Functions of peer review organizations

(a) Review of professional activities; determination of payment; determination of review authority;

consultation with professional health care practitioners; standards of health care; other duties

Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions:

(1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under subchapter XVIII of this chapter (including where payment is made for such services to eligible organizations pursuant to contracts under section 1395mm of this title) for the purpose of determining whether -

(A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

If the organization performs such reviews with respect to a type of health care practitioner other than medical doctors, the organization shall establish

procedures for the involvement of health care practitioners of that type in such reviews.

(2) The organization shall determine, on the basis of the review carried out under subparagraphs (A), (B), and (C) of paragraph (1), whether payment shall be made for services under subchapter XVIII of this chapter. Such determination shall constitute the conclusive determination on those issues for purposes of payment under subchapter XVIII of this chapter, except that payment may be made if -

(A) such payment is allowed by reason of section 1395pp of this title;

42 U.S.C. Section 1395g. Payments to providers of services

(a) Determination of amount

The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the General Accounting Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period.

42 U.S.C. Section 1395x(v)(1)(A)(ii)

(v) Reasonable costs

(1)(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance

programs established under this subchapter, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this subchapter) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

42 U.S.C. Section 1395ff. Determinations; appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a utilization and quality control peer review organization under section 1320c-3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w-22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI of this chapter.

42 U.S.C. Section 1395ff(b)(1)(A)

(b) Appeal rights

(1) In general

(A) Reconsideration of initial determination

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 405 of this title shall be considered a reference

to the "Secretary" or the "Department of Health and Human Services", respectively.

42 U.S.C. Section 1395ff(b)(1)(G)

(G) Reopening and revision of determinations

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

42 U.S.C. Section 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

42 U.S.C. Section 1395kk. Administration of insurance programs

(a) Functions of Secretary; performance directly or by contract

Except as otherwise provided in this subchapter and in the Railroad Retirement Act of 1974 (45 U.S.C. 231 et seq.), the insurance programs established by this subchapter shall be administered by the Secretary. The Secretary may perform any of his functions under this subchapter directly, or by contract providing for payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.

42 U.S.C. Section 1395kk-1 Contracts with medicare administrative contractors

(a) Authority.—

(1) Authority To Enter Into Contracts.—

The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

42 U.S.C. 1395kk-1(a)(4)(A)

(4) Functions Described.—

The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1869(f)(2)(B)), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

(A) Determination of Payment Amounts.—

Determining (subject to the provisions of section 1395oo and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this subchapter to be made to providers of services, suppliers and individuals.

42 U.S.C Section 1395pp. Limitation on liability where claims are disallowed

(a) Conditions prerequisite to payment for items and services notwithstanding determination of disallowance

Where -

(1) a determination is made that, by reason of section 1395y(a)(1) or (9) of this title or by reason of a coverage denial described in subsection (g) of this section, payment may not be made under part A or part B of this subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u(b)(3)(B)(ii) of this title, and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B of this subchapter, then to the extent permitted by this subchapter, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this subchapter), as though section 1395y(a)(1) and section 1395y(a)(9) of this title did not apply and as though the coverage denial described in subsection (g) of this section had not occurred.

REGULATIONS

42 C.F.R. Sec. 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

42 C.F.R. Sec. 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) General. Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be--

(1) Suspended, in whole or in part, by CMS, an intermediary, or a carrier if CMS, the intermediary, or the carrier possesses reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct, although additional evidence may be needed for a determination; or

(2) Offset or recouped, in whole or in part, by an intermediary or a carrier if the intermediary, carrier, or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

42 C.F.R. Sec. 405.806 Effect of Initial Determination.

The initial determination is binding upon all parties to the claim for benefits unless the determination is--

(a) Reviewed in accordance with Sec. Sec. 405.810 through 405.812; or

(b) Revised as a result of a reopening in accordance with Sec. 405.841.

42 C.F.R. Sec. 405.841 Reopening initial or review determination of the carrier, and decision of a carrier hearing officer.

An initial or review determination of a carrier or a decision of a hearing officer may be reopened by such carrier or hearing officer:

(a) Within 12 months from the date of the notice of such initial or review determination or decision to the party to such determination or decision; or

(b) After such 12-month period, but within 4 years from the date of the notice of the initial determination to the party to such determination, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(c) At any time, when:

(1) Such initial or review determination or decision was procured by fraud or similar fault of the beneficiary or some other person, or

(2) Such initial or review determination or decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error or error on the face of the evidence on which such determination or decision was based.

42 C.F.R. Sec. 405.1803(c) Intermediary determination and notice of amount of program reimbursement.

(c) Use of notice as basis for recoupment of overpayments. The intermediary's determination

contained in its notice is the basis for making the retroactive adjustment (required by Sec. 413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including recoupment under Sec. 405.373 from ongoing payments to the provider of any overpayments to the provider identified in the determination. Recoupment is made notwithstanding

42 C.F.R. Sec. 405.1807 Effect of intermediary determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) An intermediary hearing is requested in accordance with Sec. 405.1811 and an intermediary hearing decision rendered in accordance with Sec. 405.1831; or

(b) The intermediary determination is revised in accordance with Sec. 405.1885; or

(c) A Board hearing is requested in accordance with Sec. 405.1835 and a hearing decision rendered pursuant thereto.

42 C.F.R. Sec. 476.71 QIO review requirements.

(a) Scope of QIO review. In its review, the QIO must determine (in accordance with the terms of its contract)--

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to

pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

42 C.F.R. Sec. 476.86 Correlation of Title XI functions with Title XVIII functions.

(a) Payment determinations. (1) QIO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

* * *

(4) QIO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

42 C.F.R. Sec. 421.100(c) Intermediary functions.

(c) Provider audits. The intermediary must audit the records of providers of services as necessary to assure proper payments.

Supreme Court, U.S.
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No. 04-1492

In the Supreme Court of the United States

LAHEY CLINIC HOSPITAL, INC., PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether 42 U.S.C. 405(h) and other provisions of the Medicare statute preclude the district court from exercising subject matter jurisdiction under 28 U.S.C. 1345 over the United States' action for restitution of Medicare overpayments.

2. Whether the doctrine of primary jurisdiction required the district court to defer its jurisdiction pending the government's exhaustion of administrative remedies.

3. Whether the prudential doctrines of exhaustion of administrative remedies and ripeness precluded the United States' action in this case.

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In the Supreme Court of the United States

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LAHEY CLINIC HOSPITAL, INC., PETITIONER

v.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-36a) is reported at 399 F.3d 1. The memorandum of decision of the district court (Pet. App. 37a-43a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 4, 2005. The petition for a writ of certiorari was filed on May 5, 2005. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Medicare Program, established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, is a federally subsidized health insurance program for the elderly and certain disabled people. See 42

U.S.C. 1395c, 1395d. Part A of the program provides insurance for covered inpatient hospital and related post-hospital services. 42 U.S.C. 1395d. Part B is a voluntary supplementary insurance program covering physicians' services and certain other medical and health services. 42 U.S.C. 1395k, 1395*l*, 1395x(s).

Among other health services, Medicare Part B covers qualifying laboratory tests administered by a hospital and furnished to outpatients for the purpose of diagnostic study. 42 U.S.C. 1395x(s)(2)(C); 42 C.F.R. 410.28. In general, such services must be reasonable and necessary for the diagnosis or treatment of illness or injury, 42 U.S.C. 1395y(a)(1)(A), and are covered only if ordered by a treating physician who uses the test results in the management of the beneficiary's specific medical problem. 42 C.F.R. 410.32.

2. This action arises out of allegations that petitioner, the Lahey Clinic Hospital, billed Medicare for tests and other diagnostic procedures performed by its clinical laboratory that were not reasonable and necessary for the diagnosis or treatment of illness or injury. The United States filed in federal district court a complaint seeking restitution of overpayments made on those claims. The complaint alleges that the government has equitable and common law causes of action based on unjust enrichment and payment under mistake of fact, and that the district court has subject matter jurisdiction pursuant to 28 U.S.C. 1345. Pet. App. 6a-7a.

Petitioner moved for judgment on the pleadings or, in the alternative, summary judgment. Pet. App. 39a. Petitioner principally argued that the United States must seek to collect alleged overpayments exclusively through recoupment actions initiated by the Secretary of Health and Human Services under the Medicare Act

and regulations. Petitioner maintained that the Medicare Act, in 42 U.S.C. 405(h), which is incorporated into the Medicare Act by 42 U.S.C. 1395ii, requires exhaustion of administrative remedies and divests district courts of jurisdiction over restitutionary suits commenced by the United States. Petitioner also argued that the doctrines of primary jurisdiction, exhaustion, and ripeness required the district court to postpone the assumption of jurisdiction until the government pursued its remedies under Medicare regulations.

The district court denied petitioner's motion. Pet. App. 37a-43a. The court reasoned that Section 405(h) contemplates exhaustion and preclusion of jurisdiction only in those cases brought *against* the government, not cases brought *by* the government. *Id.* at 40a-41a. The court concluded that the policy reasons for requiring providers to resort initially to Medicare's administrative remedies do not apply when the government is the plaintiff. *Id.* at 41a-42a. The court also held that deferring the assumption of jurisdiction on prudential grounds until the Secretary makes a final administrative decision would be inconsistent with a statutory scheme in which "the Secretary may specify such requirements for exhaustion as he deems serve his own interests in effective and efficient administration." *Id.* at 42a & 43a n.3 (quoting *Weinberger* v. *Salfi*, 422 U.S. 749, 766 (1975)). The court certified its order for interlocutory appeal under 28 U.S.C. 1292(b). Pet. App. 8a, 42a.

3. The court of appeals affirmed. Pet. App. 1a-36a. The court held that 28 U.S.C. 1345 vests district courts with original jurisdiction over common law actions brought by the United States, and that nothing in the Medicare Act expressly or impliedly repeal the broad grant of jurisdiction conferred by Section 1345. The

court explained that 42 U.S.C. 405(h), which channels claims arising under the Medicare Act through the Act itself and bars judicial actions *against* the United States under 28 U.S.C. 1346 as well as federal question jurisdiction under 28 U.S.C. 1331, makes no reference to claims *brought by* the United States under 28 U.S.C. 1345. Pet. App. 16a-17a.

The court also reasoned that Congress did not intend the Medicare Act to displace the government's long-standing common law remedies to recover monies wrongly paid from the Treasury. It noted that the United States has a well-established right to bring such actions, even absent statutory authorization to sue. The court of appeals further reasoned that there is a strong presumption against construing statutes to limit common law remedies or to divest the United States of its pre-existing sovereign rights. Pet. App. 22a-26a.

With respect to petitioners' argument that the district court should refer to the dispute to the Secretary asa prudential matter under the doctrine of primary jurisdiction, the court concluded that the issue was not within the scope of the certification under 28 U.S.C. 1292(b). In addition, the court observed that even it "arguably had some form of supplemental appellate jurisdiction to reach the question," it saw no basis to upset the district court's ruling. Pet. App. 27a.

ARGUMENT

The court of appeals decision is correct, and does not conflict with any decision of this Court or the decisions of other courts of appeals. The petition should therefore be denied.

1. The court of appeals correctly held that the district court has jurisdiction under 28 U.S.C. 1345 over

the United States's claims in this case for restitution of Medicare overpayments. Section 1345 provides:

> Except as otherwise provided by Act of Congress, the district courts shall have original jurisdiction of all civil actions, suits or proceedings commenced by the United States, or by an agency or officer thereof expressly authorized to sue by Act of Congress.

28 U.S.C. 1345. As indicated by the introductory proviso to that provision, Congress by statute may limit federal court jurisdiction over suits brought by the United States. This Court has made held, however, that any such limitation will not be found by mere implication; a clear expression of congressional intent is required. *Colorado River Water Conservation Dist.* v. *United States*, 424 U.S. 800, 808 (1976); *United States* v. *Puerto Rico*, 721 F.2d 832, 835-837 (1st Cir. 1983). Petitioner points to no Act of Congress that expressly bars jurisdiction in this case.

a. Petitioner argues that 42 U.S.C. 405(h) limits the jurisdiction conferred by 28 U.S.C. 1345. Pet. 8-14. The court of appeals correctly rejected that contention. Section 405(h), which has been incorporated into the Medicare Act by 42 U.S.C. 1395ii, provides:

> The findings and decisions of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to

> recover on any claim arising under this subchapter.

42 U.S.C. 405(h).

This Court has held that Section 405(h) channels Medicare claims brought by providers and beneficiaries against the government and arising under the Medicare Act through a comprehensive scheme that makes judicial review of a decision of the Secretary contingent on exhaustion of administrative remedies and bars judicial review under 28 U.S.C. 1331. *Shalala* v. *Illinois Council on Long Term Care*, 529 U.S. 1, 7-14 (2000); *Heckler* v. *Ringer*, 466 U.S. 602, 614-619 (1984); see also *Weinberger* v. *Salfi*, 422 U.S. 749, 760-761 (1975) (claims under Social Security Act). As the court of appeals held, however, Section 405(h) does not purport to apply to actions brought *by* the government *against* a Medicare provider. Quite to the contrary, while Section 405(h) bars "federal question" jurisdiction under 28 U.S.C. 1331 and "United States as *defendant*" jurisdiction under 28 U.S.C. 1346, Section 405(h) conspicuously omits any reference to actions brought by the government under the "United States as *plaintiff*" jurisdiction conferred by 28 U.S.C. 1345. That omission strongly supports "congressional intent to preserve jurisdiction under § 1345." Pet. App. 16a.

Contrary to petitioner's contention (Pet. 10, 12), the court of appeals' construction of Section 405(h) does not conflict with *Weinberger* v. *Salfi*, *supra*. That decision did not involve a claim by the Untied States. It involved asserted jurisdiction under 28 U.S.C. 1331 over a suit filed against the Secretary by applicants for Social Security benefits. 422 U.S. at 755. And *Weinberger* v. *Salfi* makes clear that the second sentence of Section 405(h), upon which petitioners rely (Pet. 10), reflects